ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 1.5 mg/ml oral suspension for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Meloxicam 1.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate	5 mg
Saccharin sodium	
Sodium carboxyl methyl cellulose	
Colloidal silicon dioxide	
Citric acid monohydrate	
Sorbitol solution	
Disodium hydrogen-phosphate dodecahydrate	
Honey flavour	
Purified water	

A yellow coloured suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

3.3 Contraindications

Do not use in pregnant or lactating animals.
Do not use in dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs less than 6 weeks of age.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Inflacam 0.5 mg/ml oral suspension for cats should be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, Lethargy Vomiting, Diarrhoea, Blood in faeces[1], Haemorrhagic diarrhoea, Haematemesis, Gastric ulcer, Small intestine ulcer, Large intestine ulcer Elevated liver enzymes Renal failure

[1]occult.

These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period should however take into account the pharmacokinetic properties of the veterinary medicinal products previously used.

3.9 Administration routes and dosage

Oral use.

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose of the veterinary medicinal product can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

Shake well before use. To be administered orally either mixed with food or directly into the mouth.

The suspension can be given using the measuring syringe provided in the package of the veterinary medicinal product. The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg body weight). Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.

A clinical response is normally seen within 3 to 4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

Avoid introduction of contamination during use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose, symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06.

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

4.3 Pharmacokinetics

Absorption
Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 7.5 hours. When the product is used according to the recommended dosage regime, steady state concentrations of meloxicam in plasma are reached on the second day of treatment.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range. Approximately 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg.

Metabolism
Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a half-life of 24 hours. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

15 ml HDPE bottle with a tamper resistant child-proof closure or 42, 100 or 200 ml polyethylene terephthalate (PET) bottle with a tamper resistant child-proof closure and two polypropylene measuring syringes: one for small dogs (up to 20 kg) and one for bigger dogs (up to 60 kg).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/134/001 15 ml
EU/2/11/134/002 42 ml
EU/2/11/134/003 100 ml
EU/2/11/134/004 200 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/12/2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 20 mg/ml solution for injection for cattle, pigs and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Meloxicam 20 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethanol (96 %)	159.8 mg
Poloxamer 188	
Macrogol 400	
Glycine	
Sodium hydroxide	
Hydrochloric acid, concentrated	
Meglumine	
Water for injections	

A clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs and horses.

3.2 Indications for use for each target species

Cattle
For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.
For the relief of post-operative pain following dehorning in calves.

Pigs
For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses
For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.
For the relief of pain associated with equine colic.

3.3 Contraindications

Do not use in horses less than 6 weeks of age.
Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.
See also section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Treatment of calves with the veterinary medicinal product 20 minutes before dehorning reduces post-operative pain. The veterinary medicinal product alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.
In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Accidental self-injection may give rise to pain.
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Common (more than 1 but less than 10 animals in 100 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[2].

[1]Slight and transient following subcutaneous administration
[2]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1].

[1]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1].
Undetermined frequency (cannot be estimated from the available data):	Injection site swelling[2]

[1]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.
[2]Transient, that resolves without intervention.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Cattle and pigs: Can be used during pregnancy and lactation.
Horses: Do not use in pregnant or lactating mares.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

3.9 Administration routes and dosage

Subcutaneous use (cattle).
Intramuscular use (pigs).
Intravenous use (cattle, horses).

Cattle
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

Horses
Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3 ml/100 kg body weight).

For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo – skeletal disorders, Inflacam 15 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

Avoid introduction of contamination during use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose, symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle
Meat and offal: 15 days.
Milk: 5 days.

Pigs
Meat and offal: 5 days.

Horses
Meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06.

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, anti-exudative, analgesic and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by *E. coli* endotoxin administration in calves, lactating cows and pigs.

4.3 Pharmacokinetics

Absorption
After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max} values of 2.1 mcg/ml and 2.7 mcg/ml were reached after 7.7 hours and 4 hours in young cattle and lactating cows, respectively.
After two intramuscular doses of 0.4 mg meloxicam/kg, a C_{max} value of 1.9 mcg/ml was reached after 1 hour in pigs.

Distribution

More than 98 % of meloxicam is bound to plasma proteins. The highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

Metabolism
Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. In pigs, bile and urine contain only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive. The metabolism in horses has not been investigated.

Elimination
Meloxicam is eliminated with a half-life of 26 hours and 17.5 hours after subcutaneous injection in young cattle and lactating cows, respectively.
In pigs, after intramuscular administration the mean plasma elimination half-life is approximately 2.5 hours.
In horses, after intravenous injection meloxicam is eliminated with a terminal half-life of 8.5 hours. Approximately 50 % of the administered dose is eliminated via urine and the remainder via faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 colourless glass injection vial containing 20 ml, 50 ml, 100 ml or 250 ml. Each vial is closed with a rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/134/005 20 ml
EU/2/11/134/006 50 ml
EU/2/11/134/007 100 ml
EU/2/11/134/008 250 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/12/2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 15 mg/ml oral suspension for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Meloxicam 15 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate	5 mg
Saccharin sodium	
Carmellose sodium	
Silica, colloidal anhydrous	
Citric acid monohydrate	
Sorbitol, liquid (non-crystallising)	
Disodium phosphate dodecahydrate	
Honey aroma	
Purified water	

White to off-white viscous oral suspension.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses.

3.3 Contraindications

Do not use in pregnant or lactating mares.
Do not use in horses suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses less than 6 weeks of age.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, Lethargy Diarrhoea[1], Abdominal pain, Colitis. Urticaria[1,2], Anaphylactoid reaction[3].

[1]Reversible
[2]Slight
[3]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Laboratory studies in cattle have not provided any evidence for teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses. Therefore the use in this species is not recommended during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticoids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

3.9 Administration routes and dosage

To be administered either mixed with food or directly into the mouth at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days. In case the veterinary medicinal product is mixed with food, it should be added to a small quantity of food, prior to feeding.

The suspension should be given using the measuring syringe provided in the package of the veterinary medicinal product. The syringe fits onto the bottle and has a 2 ml scale.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

Shake well before use.

After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

Avoid introduction of contamination during use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 3 days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06.

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by intravenous *E. coli* endotoxin administration in calves and pigs.

4.3 Pharmacokinetics

Absorption
When the product is used according to the recommended dosage regime, the oral bioavailability is approximately 98 %. Maximal plasma concentrations are obtained after approximately 2–3 hours. The accumulation factor of 1.08 suggests that meloxicam does not accumulate when administered daily.

Distribution
Approximately 98 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.12 l/kg.

Metabolism
The metabolism is qualitatively similar in rats, mini-pigs, humans, cattle and pigs, although quantitatively there are differences. The major metabolites found in all species were the 5-hydroxy- and 5-carboxy- metabolites and the oxalyl- metabolite. The metabolism in horses was not investigated. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a terminal half-life of 7.7 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 3 months.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

HDPE bottle containing 100 or 250 ml with a tamper resistant proof child-proof closure and a polypropylene measuring syringe.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/134/009 100 ml
EU/2/11/134/010 250 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/12/2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 1 mg chewable tablets for dogs
Inflacam 2.5 mg chewable tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substance:

Meloxicam	1 mg
Meloxicam	2.5 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Silicified microcrystalline cellulose
Sodium acid citrate
Crospovidone
Talc
Pork flavour
Magnesium stearate

Pale-yellow, single-scored, chewable tablets that can be divided into equal halves.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

3.3 Contraindications

Do not use in pregnant or lactating animals.
Do not use in dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs less than 6 weeks of age or less than 4 kg body weight.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

This product for dogs should not be used in cats as it is not suitable for use in this species.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, Lethargy Vomiting, Diarrhoea, Blood in faeces[1], Haemorrhagic diarrhoea, Haematemesis, Gastric ulcer, Small intestine ulcer, Large intestine ulcer Elevated liver enzymes Renal failure

[1]occult

These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period should however take into account the pharmacokinetic properties of the veterinary medicinal products previously used.

3.9 Administration routes and dosage

Oral use.

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day.

Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.

Each chewable tablet contains either 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg body weight dog, or a 25 kg body weight dog respectively.
Each chewable tablet can be halved for accurate dosing according to the individual body weight of the dog.
To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.
The veterinary medicinal products can be administered with or without food, are flavoured and are taken by most dogs voluntarily.

Dose scheme for the maintenance dose:

Body weight (kg)	Number of chewable tablets		mg/kg
	1 mg	2.5 mg	
4–7	½		0.13–0.1
7.1–10	1		0.14–0.1
10.1–15	1½		0.15–0.1
15.1–20	2		0.13–0.1
20.1–25		1	0.12–0.1
25.1–35		1½	0.15–0.1
35.1–50		2	0.14–0.1

The use of Inflacam oral suspension for dogs may be considered for an even more precise dosing. For dogs weighing less than 4 kg, the use of Inflacam oral suspension for dogs is recommended.

A clinical response is normally seen within 3–4 days. Treatment should be discontinued after 10 days if no clinical improvement is apparent.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose, symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06.

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

4.3 Pharmacokinetics

Absorption
Meloxicam is completely absorbed following oral administration and maximal plasma concentrations are obtained after approximately 4.5 hours. When the product is used according to the recommended dosage regime, steady state concentrations of meloxicam in plasma are reached on the second day of treatment.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range. Approximately 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg.

Metabolism
Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a half-life of 24 hours. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

PVC/PVDC blister packs with a 20 micron foil.

Pack sizes: 20 and 100 tablets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/134/011	1 mg, 20 tablets.
EU/2/11/134/012	1 mg, 100 tablets.
EU/2/11/134/013	2.5 mg, 20 tablets.
EU/2/11/134/014	2.5 mg, 100 tablets.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/12/2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 5 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Meloxicam 5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethanol (96 %)	159.8 mg
Poloxamer 188	
Macrogol 400	
Glycine	
Disodium edetate	
Sodium hydroxide	
Hydrochloric acid, concentrated	
Meglumine	
Water for injections.	

A clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

Dogs
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats
Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

3.3 Contraindications

Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals less than 6 weeks of age nor in cats of less than 2 kg.

Refer to section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

During anaesthesia, monitoring and fluid therapy should be considered as standard practice.

Any oral follow-up therapy using meloxicam or other NSAIDs should not be administered in cats, as appropriate dosage regimens for such follow-up treatments have not been established.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Accidental self-injection may give rise to pain.
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, Lethargy Vomiting, Diarrhoea, Blood in faeces[1], Haemorrhagic diarrhoea[2], Haematemesis[2], Gastric ulcer[2], Small intestine ulcer[2], Large intestine ulcer[2] Elevated liver enzymes Renal failure Anaphylactoid reaction[3]

[1]Occult
[2]These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
[3]If such reaction occurs, it should be treated symptomatically.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating animals.

3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic drugs should be avoided. In animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period should however take into account the pharmacological properties of the veterinary medicinal products previously used.

3.9 Administration routes and dosage

Subcutaneous or intravenous use (dogs).
Subcutaneous use (cats).

Dogs
Musculo-skeletal disorders:
Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight).

Inflacam 1.5 mg/ml oral suspension for dogs or Inflacam 1 mg and 2.5 mg chewable tablets for dogs may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Reduction of post-operative pain (over a period of 24 hours):
Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight) before surgery, for example at the time of induction of anaesthesia.

Cats
Reduction of post-operative pain:
Single subcutaneous injection at a dosage of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

Avoid introduction of contamination during use.

Maximum number of piercings is 42 for all presentations.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose, symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06.

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

4.3 Pharmacokinetics

Absorption
Following subcutaneous administration, meloxicam is completely bioavailable and maximal mean plasma concentrations of 0.73 mcg/ml in dogs and 1.1 mcg/ml in cats were reached approximately 2.5 hours and 1.5 hours post administration, respectively.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range in dogs. More than 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg in dogs and 0.09 l/kg in cats.

Metabolism
In dogs, meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

In cats, meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Five major metabolites were detected all having been shown to be pharmacologically inactive. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. As for other species investigated, the main pathway of meloxicam biotransformation in cat is oxidation.

Elimination
In dogs, meloxicam is eliminated with a half-life of 24 hours. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.

In cats, meloxicam is eliminated with a half-life of 24 hours. The detection of metabolites from the parent compound in urine and faeces, but not in plasma is indicative for their rapid excretion. 21 % of the recovered dose is eliminated in urine (2 % as unchanged meloxicam, 19 % as metabolites) and 79 % in the faeces (49 % as unchanged meloxicam, 30% as metabolites).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Keep the vial in the outer carton.

5.4 Nature and composition of immediate packaging

Cardboard box containing one colourless glass injection vial of 10 ml, 20 ml or 100 ml, closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/134/015 10 ml
EU/2/11/134/016 20 ml
EU/2/11/134/017 100 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/12/2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 5 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Meloxicam 5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Ethanol (96 %)	159.8 mg
Poloxamer 188	
Macrogol 400	
Glycine	
Disodium edetate	
Sodium hydroxide	
Hydrochloric acid, concentrated	
Meglumine	
Water for injections	

A clear, yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves and young cattle) and pigs.

3.2 Indications for use for each target species

Cattle
For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For the relief of post-operative pain following dehorning in calves.

Pigs
For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For the relief of post-operative pain associated with minor soft tissue such as castration.

3.3 Contraindications

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.
Do not use in pigs less than 2 days old.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Treatment of calves with the veterinary medicinal product 20 minutes before dehorning reduces post-operative pain. The veterinary medicinal product alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

Treatment of piglets with the veterinary medicinal product before castration reduces post-operative pain. To obtain pain relief during surgery co-medication with an appropriate anaesthetic/sedative is needed.

To obtain the best possible pain relieving post-surgery the veterinary medicinal product should be administered 30 minutes before surgical intervention.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Accidental self-injection may give rise to pain.
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Common (more than 1 but less than 10 animals in 100 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[2].

[1]Slight and transient following subcutaneous administration

[2]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1].

[1]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Cattle: Can be used during pregnancy.
Pigs: Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

3.9 Administration routes and dosage

Cattle
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 10 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs
Locomotor disorders:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2 ml/25 kg body weight). If required, a second administration of meloxicam can be given after 24 hours.

Reduction of post-operative pain
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 0.4 ml/5 kg body weight) before surgery.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

Avoid introduction of contamination during use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose, symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle
Meat and offal: 15 days.

Pigs
Meat and offal: 5 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06.

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, anti-exudative, analgesic and antipyretic effects. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B2 induced by *E. coli* endotoxin administration in calves and pigs.

4.3 Pharmacokinetics

Absorption
After a single subcutaneous dose of 0.5 mg meloxicam/kg, C_{max} values of 2.1 mcg/ml were reached after 7.7 hours in young cattle.
Following single intramuscular doses of 0.4 mg meloxicam/kg, a C_{max} value of 1.1 to 1.5 mcg/ml was reached within 1 hour in pigs.

Distribution
More than 98 % of meloxicam is bound to plasma proteins. The highest meloxicam concentrations are to be found in liver and kidney. Comparatively low concentrations are detectable in skeletal muscle and fat.

Metabolism
Meloxicam is predominantly found in plasma. In cattle, meloxicam is also a major excretion product in milk and bile whereas urine contains only traces of the parent compound. In pigs, bile and urine contain only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a half-life of 26 hours after subcutaneous injection in young cattle. In pigs, after intramuscular administration the mean plasma elimination half-life is approximately 2.5 hours.

Approximately 50 % of the administered dose is eliminated via urine and the remainder via faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 colourless glass injection vial containing 20 ml, 50 ml, or 100 ml, closed with a rubber stopper and sealed with an aluminium cap.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/134/018 20 ml
EU/2/11/134/019 50 ml
EU/2/11/134/020 100 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/12/2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 330 mg granules for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Active substance:
Meloxicam 330 mg

Excipients:

Qualitative composition of excipients and other constituents
Glucose monohydrate
Povidone
Apple flavour (containing butylated hydroxyanisole (E320))
Crospovidone

Pale yellow granules.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses weighing between 500 and 600 kg.

3.3 Contraindications

Do not use in pregnant or lactating mares.
Do not use in horses suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses less than 6 weeks of age.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

In order to minimise the risk of intolerance, the veterinary medicinal product should be mixed into muesli feed.
This veterinary medicinal product is only for use in horses weighing between 500 and 600 kg.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, Lethargy Diarrhoea[1], Abdominal pain, Colitis. Urticaria[1,2],Anaphylactoid reactions[3].

[1]Reversible
[2]Slight
[3]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Laboratory studies in cattle have not provided any evidence of teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses. Therefore, the use in horses is not recommended during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer concurrently with glucocorticoids, other NSAIDs or with anti-coagulant agents.

3.9 Administration routes and dosage

In-feed use.

To be administered mixed with food at a dose of 0.6 mg/kg body weight, once daily, up to 14 days. The veterinary medicinal product should be added to 250 g of muesli feed, prior to feeding.

Each sachet contains one dose for a horse weighing between 500 and 600 kg and the dose must not be divided into smaller doses.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

Avoid introduction of contamination during use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose, symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 3 days.
Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06.

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by intravenous *E. coli* endotoxin administration in calves and pigs.

4.3 Pharmacokinetics

Absorption
When the product is used according to the recommended dosage regime, the oral bioavailability is approximately 98 %. Maximal plasma concentrations are obtained after approximately 2–3 hours. The accumulation factor of 1.08 suggests that meloxicam does not accumulate when administered daily.

Distribution
Approximately 98 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.12 l/kg.

Metabolism
The metabolism is qualitatively similar in rats, humans, cattle and pigs (including mini-pigs), although quantitatively there are differences. The major metabolites found in all species were the 5-hydroxy- and 5-carboxy- metabolites and the oxalyl- metabolite. The metabolism in horses was not investigated. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a terminal half-life of 7.7 hours.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after incorporation into muesli feed: use immediately.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Paper foil sachets (paper/PE/alu/PE) containing 1.5 g granules per sachet in a cardboard box.
Pack size: 20 and 100 sachets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/134/022 20 sachets.
EU/2/11/134/021 100 sachets.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/12/2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 0.5 mg/ml oral suspension for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Meloxicam 0.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate	1.5 mg
Glycerol	
Citric acid monohydrate	
Xanthan gum	
Povidone	
Sodium dihydrogen phosphate monohydrate	
Simethicone emulsion	
Honey flavour	
Silica, colloidal anhydrous	
Water, purified	

A smooth light yellow suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.
Alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats.

3.3 Contraindications

Do not use in pregnant or lactating animals.
Do not use in cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats less than 6 weeks of age.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

Post-operative pain and inflammation following surgical procedures:
In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders:
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, Lethargy. Vomiting, Diarrhoea, Blood in faeces[1], Gastric ulcer, Small intestine ulcer, Large intestine ulcer. Elevated liver enzymes. Renal failure.

[1]occult

These side effects are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section 3.3).

3.8 Interaction with other medicinal products and other forms of interaction

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic veterinary medicinal products should be avoided.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period should however take into account the pharmacological properties of the veterinary medicinal products previously used.

3.9 Administration routes and dosage

Oral use.

Post-operative pain and inflammation following surgical procedures:
After initial treatment with Inflacam 5 mg/ml solution for injection for cats, continue treatment 24 hours later with Inflacam 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight (0.1 ml /kg). The oral follow-up dose may be administered once daily (at 24-hour intervals) for up to four days.

Acute musculo-skeletal disorders:
Initial treatment is a single oral dose of 0.2 mg meloxicam/kg body weight (0.4 ml/kg) on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a dose of 0.05 mg meloxicam/kg body weight (0.1 ml/kg) for as long as acute pain and inflammation persist.

Chronic musculo-skeletal disorders:
Initial treatment is a single oral dose of 0.1 mg meloxicam/kg body weight (0.2 ml/kg) on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.05 mg meloxicam/kg body weight (0.1 ml /kg). A clinical response is normally seen within 7 days. Treatment should be discontinued after 14 days at the latest if no clinical improvement is apparent.

Route and method of administration
A one ml syringe is provided with the product. The precision of the syringe is not suitable for the treatment of cats below 1 kg.

Shake well before use. To be administered orally either mixed with food or directly into the mouth.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

Avoid introduction of contamination during use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Meloxicam has a narrow therapeutic safety margin in cats and clinical signs of overdose may be seen at relatively small overdose levels.
In case of overdose, adverse reactions, as listed in section 3.6, are expected to be more severe and more frequent. In case of overdose symptomatic treatment should be initiated.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AC06.

4.2 Pharmacodynamics

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. *In vitro* and *in vivo* studies demonstrated that meloxicam inhibits cyclooxygenase-2 (COX-2) to a greater extent than cyclooxygenase-1 (COX-1).

4.3 Pharmacokinetics

Absorption
If the animal is fasted when dosed, the maximal plasma concentrations are obtained after approximately 3 hours. If the animal is fed at the time of dosing, the absorption may be slightly delayed.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range. Approximately 97 % of meloxicam is bound to plasma proteins.

Metabolism
Meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Five major metabolites were detected all having been shown to be pharmacologically inactive. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. As for other species investigated, the main pathway of meloxicam biotransformation in cat is oxidation.

Elimination
Meloxicam is eliminated with a half-life of 24 hours. The detection of metabolites from the parent compound in urine and faeces, but not in plasma is indicative for their rapid excretion. 21% of the recovered dose is eliminated in urine (2 % as unchanged meloxicam, 19 % as metabolites) and 79 % in the faeces (49 % as unchanged meloxicam, 30 % as metabolites).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging:
3 ml and 5 ml bottle: 14 days.
10 ml and 15 ml bottle: 6 months.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

White high density polyethylene bottle containing 10 ml or 15 ml with a tamper resistant child-proof closure.
Polypropylene bottle containing 3 ml or 5 ml with a tamper resistant child-proof closure.

Each bottle is packed in a cardboard box with a 1 ml measuring syringe (barrel in polypropylene and plunger/piston in high density polyethylene).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/134/023 10 ml
EU/2/11/134/024 15 ml
EU/2/11/134/025 3 ml
EU/2/11/134/026 5 ml

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09/12/2011

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (15 ml, 42 ml, 100 ml and 200 ml bottle).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 1.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

3. PACKAGE SIZE

15 ml
42 ml
100 ml
200 ml

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months, by __ / __ / __

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/134/001	15 ml
EU/2/11/134/002	42 ml
EU/2/11/134/003	100 ml
EU/2/11/134/004	200 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE (100 ml and 200 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 1.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 6 months.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE (15 ml and 42 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (20 ml, 50 ml, 100 ml and 250 ml bottle).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. PACKAGE SIZE

20 ml
50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle, pigs and horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: s.c. or i.v. use.

Pigs: i.m. use.

Horses: i.v. use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle: meat and offal: 15 days; milk: 5 days.
Pigs: meat and offal: 5 days.
Horses: meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days, by __ / __ / __

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/134/005	20 ml
EU/2/11/134/006	50 ml
EU/2/11/134/007	100 ml
EU/2/11/134/008	250 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE (50, 100 ml and 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. TARGET SPECIES

Cattle, pigs and horses.

4. ROUTES OF ADMINISTRATION

Cattle: s.c. or i.v. use.
Pigs: i.m. use.
Horses: i.v. use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle: Meat and offal: 15 days; Milk: 5 days.

Pigs: Meat and offal: 5 days.

Horses: Meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE (20 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (100 ml or 250 ml bottle).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 15 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 15 mg/ml

3. PACKAGE SIZE

100 ml
250 ml

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 3 days.
Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months, by __ / __ / __.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/134/009 100 ml
EU/2/11/134/010 250 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE (100 ml and 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 15 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 15 mg/ml

3. TARGET SPECIES

Horses.

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 3 days.
Not authorised for use in animals producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 3 months.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (20 tablets, 100 tablets).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 1 mg chewable tablets
Inflacam 2.5 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each chewable tablet contains:

Meloxicam 1 mg
Meloxicam 2.5 mg

3. PACKAGE SIZE

20 chewable tablets
100 chewable tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/134/011	1 mg, 20 chewable tablets.
EU/2/11/134/012	1 mg, 100 chewable tablets.
EU/2/11/134/013	2.5 mg, 20 chewable tablets.
EU/2/11/134/014	2.5 mg, 100 chewable tablets.

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER (20 tablets and 100 tablets).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each chewable tablet contains:

Meloxicam 1 mg
Meloxicam 2.5 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (10 ml, 20 ml, 100 ml vials).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. PACKAGE SIZE

10 ml
20 ml
100 ml

4. TARGET SPECIES

Dogs and cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dogs: s.c. or i.v. use.
Cats: s.c. use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days, by __ / __ / __.

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/134/015	10 ml
EU/2/11/134/016	20 ml
EU/2/11/134/017	100 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. TARGET SPECIES

Dogs and cats.

4. ROUTES OF ADMINISTRATION

Dogs: s.c. or i.v. use.
Cats: s.c. use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days, by __ / __ / __.

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIALS (10 ml and 20 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (20 ml, 50 ml, 100 ml vials).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. PACKAGE SIZE

20 ml
50 ml
100 ml

4. TARGET SPECIES

Cattle (calves and young cattle) and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: s.c. or i.v. use.
Pigs: i.m. use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle: meat and offal: 15 days.
Pigs: meat and offal: 5 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days, by __ / __ / __.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/134/018	20 ml
EU/2/11/134/019	50 ml
EU/2/11/134/020	100 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL (100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. TARGET SPECIES

Cattle (calves and young cattle) and pigs.

4. ROUTES OF ADMINISTRATION

Cattle: s.c. or i.v. use.
Pigs: i.m. use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Cattle: meat and offal: 15 days.
Pigs: meat and offal: 5 days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days, by __ / __ / __.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL (20 ml and 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam. 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (20 sachets or 100 sachets).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 330 mg granules

2. STATEMENT OF ACTIVE SUBSTANCES

Each sachet contains:

Meloxicam 330 mg

3. PACKAGE SIZE

20 sachets
100 sachets

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

In feed use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 3 days.
Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once incorporated into feed, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/134/022 20 sachets
EU/2/11/134/021 100 sachets

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SACHET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each sachet contains:

Meloxicam 330 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX (3 ml, 5 ml, 10 ml and 15 ml bottle).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 0.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 0.5 mg/ml

3. PACKAGE SIZE

3 ml
5 ml
10 ml
15 ml

4. TARGET SPECIES

Cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
3 ml: Once opened use within 14 days, by __ / __ / __.
5 ml: Once opened use within 14 days, by __ / __ / __.
10 ml: Once opened use within 6 months, by __ / __ / __.
15 ml: Once opened use within 6 months, by __ / __ / __.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/134/023	10 ml
EU/2/11/134/024	15 ml
EU/2/11/134/025	3 ml
EU/2/11/134/026	5 ml

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE (3 ml, 5 ml, 10 ml, 15 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inflacam 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 0.5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Inflacam 1.5 mg/ml oral suspension for dogs

2. Composition

Each ml contains:

Active substance
Meloxicam 1.5 mg

Excipient
Sodium benzoate 5 mg

A yellow coloured suspension.

3. Target species

Dogs.

4. Indications for use

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

5. Contraindications

Do not use in pregnant or lactating animals.
Do not use in dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs less than 6 weeks of age.

6. Special warnings

Special precautions for safe use in the target species:
This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Inflacam 0.5 mg/ml oral suspension for cats should be used.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period should however take into account the pharmacological properties of the veterinary medicinal products previously used.

Overdose:
In case of overdose, symptomatic treatment should be initiated.

Major incompatibilities:
None known.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, Lethargy Vomiting, Diarrhoea, Blood in faeces[1], Haemorrhagic diarrhoea, Haematemesis, Gastric ulcer, Small intestine ulcer, Large intestine ulcer Elevated liver enzymes Renal failure

[1]occult.

These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Oral use.

Dosage
Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose of the veterinary medicinal product can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

Route and method of administration
Shake well before use. To be administered orally either mixed with food or directly into the mouth. The suspension can be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a kg-body weight scale, which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg body weight). Thus for initiation of the therapy on the first day, twice the maintenance dosage will be required.
A clinical response is normally seen within 3 to 4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.
Avoid introduction of contamination during use.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription**.**

14. Marketing authorisation numbers and pack sizes

Pack sizes:
EU/2/11/134/001 15 ml
EU/2/11/134/002 42 ml
EU/2/11/134/003 100 ml
EU/2/11/134/004 200 ml

15, 42, 100 or 200 ml bottle with two measuring syringes.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

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PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Inflacam 20 mg/ml solution for injection for cattle, pigs and horses

2. Composition

Each ml contains:

Active substance
Meloxicam 20 mg

Excipient
Ethanol (96 %) 159.8 mg

A clear, yellow solution.

3. Target species

Cattle, pigs and horses.

4. Indications for use

Cattle
For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.
For the relief of post-operative pain following dehorning in calves.

Pigs
For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses
For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders.
For the relief of pain associated with equine colic.

5. Contraindications

Do not use in horses less than 6 weeks of age.
Do not use in pregnant or lactating mares.
Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.
See also section “Special warnings”-“Pregnancy and lactation”.

6. Special warnings

Special precautions for safe use in the target species:
Treatment of calves with Inflacam 20 minutes before dehorning reduces post-operative pain. Inflacam alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.
In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental self-injection may give rise to pain.
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Cattle and pigs: Can be used during pregnancy and lactation.
Horses: Do not use in pregnant or lactating mares.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

Overdose:
In case of overdose, symptomatic treatment should be initiated.

Major incompatibilities:
None known.

7. Adverse events

Cattle:

Common (more than 1 but less than 10 animals in 100 animals treated)	Injection site swelling[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[2].

[1]Slight and transient following subcutaneous administration
[2]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1].

[1]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1].
Undetermined frequency (cannot be estimated from the available data):	Injection site swelling[2]

[1]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.
[2]Transient, that resolves without intervention.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Subcutaneous use (cattle).
Intramuscular use (pigs).
Intravenous use (cattle, horses).

Cattle
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

Horses
Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3 ml/100 kg body weight).

For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo-skeletal disorders, Inflacam 15 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

9. Advice on correct administration

Avoid introduction of contamination during use.
To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

10. Withdrawal periods

Cattle: meat and offal: 15 days; milk: 5 days.
Pigs: meat and offal: 5 days.
Horses: meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening of the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription**.**

14. Marketing authorisation numbers and pack sizes

EU/2/11/134/005 20 ml
EU/2/11/134/006 50 ml
EU/2/11/134/007 100 ml
EU/2/11/134/008 250 ml

Pack sizes:
20, 50, 100 or 250 ml injection vial.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:

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and

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For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Inflacam 15 mg/ml oral suspension for horses

2. Composition

Each ml contains:

Active substance
Meloxicam 15 mg

Excipient
Sodium benzoate 5 mg

White to off-white viscous suspension.

3. Target species

Horses.

4. Indications for use

Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses.

5. Contraindications

Do not use in pregnant or lactating mares.
Do not use in horses suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses less than 6 weeks of age.

6. Special warnings

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Laboratory studies in cattle have not provided any evidence of teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses. Therefore, do not use in pregnant or lactating mares.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticoids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

Overdose:
In case of overdose, symptomatic treatment should be initiated.

Major incompatibilities:
None known.

7. Adverse events

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, Lethargy Diarrhoea[1], Abdominal pain, Colitis. Urticaria[1,2], Anaphylactoid reaction[3].

[1]Reversible
[2]Slight
[3]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Oral use.

Dosage
Oral suspension to be administered at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days. This is equivalent to 1 ml of the veterinary medicinal product per 25 kg body weight of horse. For example, a horse weighing 400 kg will receive 16 ml of the veterinary medicinal product, a horse weighing 500 kg will receive 20 ml of the veterinary medicinal product, and a horse weighing 600 kg will receive 24 ml of the veterinary medicinal product.

Route and method of administration
Shake well before use. To be administered either mixed with a small quantity of food, prior to feeding, or directly into the mouth.
The suspension should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a 2 ml scale.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

The use of suitably calibrated measuring equipment is recommended.
Avoid introduction of contamination during use.
After administration of the veterinary medicinal product, close the bottle by replacing the cap, wash the measuring syringe with warm water and let it dry.

10. Withdrawal periods

Meat and offal: 3 days.
Not authorised for use in animals producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 3 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription**.**

14. Marketing authorisation numbers and pack sizes

EU/2/11/134/009 100 ml
EU/2/11/134/010 250 ml

Pack sizes:
100 or 250 ml bottle with a measuring syringe.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd.,
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For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Inflacam 1 mg chewable tablets for dogs
Inflacam 2.5 mg chewable tablets for dogs

2. Composition

Each chewable tablet contains:

Active substance

Meloxicam	1 mg
Meloxicam	2.5 mg

Pale-yellow, single-scored, chewable tablets that can be divided into equal halves.

3. Target species

Dogs.

4. Indications for use

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

5. Contraindications

Do not use in pregnant or lactating animals.
Do not use in dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs less than 6 weeks of age or less than 4 kg body weight.

6. Special warnings

Special precautions for safe use in the target species:
This product for dogs should not be used in cats as it is not suitable for use in this species.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period should however take into account the pharmacological properties of the veterinary medicinal products previously used.

Overdose:
In case of overdose, symptomatic treatment should be initiated.

Major incompatibilities:
None known.

7. Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, Lethargy Vomiting, Diarrhoea, Blood in faeces[1], Haemorrhagic diarrhoea, Haematemesis, Gastric ulcer, Small intestine ulcer, Large intestine ulcer Elevated liver enzymes Renal failure

[1]occult

These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Oral use.

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day.

Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.

Each chewable tablet contains either 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg body weight dog, or a 25 kg body weight dog respectively.
Each chewable tablet can be halved for accurate dosing according to the individual body weight of the dog.

Inflacam chewable tablets can be administered with or without food, are flavoured and are taken by most dogs voluntarily.

Dose scheme for the maintenance dose:

Body weight (kg)	Number of chewable tablets		mg/kg
	1 mg	2.5 mg	
4–7	½		0.13–0.1
7.1–10	1		0.14–0.1
10.1–15	1½		0.15–0.1
15.1–20	2		0.13–0.1
20.1–25		1	0.12–0.1
25.1–35		1½	0.15–0.1
35.1–50		2	0.14–0.1

For dogs weighing less than 4 kg, the use of Inflacam oral suspension for dogs is recommended.

A clinical response is normally seen within 3–4 days. Treatment should be discontinued after 10 days if no clinical improvement is apparent.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister packs after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription**.**

14. Marketing authorisation numbers and pack sizes

EU/2/11/134/011 1 mg, 20 tablets
EU/2/11/134/012 1 mg, 100 tablets
EU/2/11/134/013 2.5 mg, 20 tablets
EU/2/11/134/014 2.5 mg, 100 tablets

Pack sizes:
20 and 100 tablets.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

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For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Inflacam 5 mg/ml solution for injection for dogs and cats

2. Composition

Each ml contains:

Active substance
Meloxicam 5 mg

Excipient
Ethanol (96 %) 159.8 mg

A clear, yellow solution.

3. Target species

Dogs and cats.

4. Indications for use

Dogs:
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats:
Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

5. Contraindications

Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals less than 6 weeks of age, nor in cats of less than 2 kg.
Refer to section “Special warnings”-“Pregnancy and lactation”.

6. Special warnings

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.
During anaesthesia, monitoring and fluid therapy should be considered as standard practice.
Any oral follow-up therapy using meloxicam or other NSAIDs should not be administered in cats, as appropriate dosage regimens for such follow-up treatments have not been established.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental self-injection may give rise to pain.

People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating animals.

Interaction with other medicinal products and other forms of interaction:
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic veterinary medicinal products should be avoided. In animals at anaesthetic risk (e.g., aged animals), intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period should however take into account the pharmacological properties of the veterinary medicinal products previously used.

Overdose:
In case of overdose, symptomatic treatment should be initiated.

Major incompatibilities:
None known.

7. Adverse events

Dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, Lethargy Vomiting, Diarrhoea, Blood in faeces[1], Haemorrhagic diarrhoea[2], Haematemesis[2], Gastric ulcer[2], Small intestine ulcer[2], Large intestine ulcer[2] Elevated liver enzymes Renal failure Anaphylactoid reaction[3]

[1]Occult
[2]These side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.
[3]If such reaction occurs, it should be treated symptomatically.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intravenous use (dogs).
Subcutaneous use (cats, dogs).

Dogs:
Musculo-skeletal disorders:
Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg). Inflacam 1.5 mg/ml oral suspension for dogs or Inflacam 1 mg and 2.5 mg chewable tablets for dogs may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Reduction of post-operative pain (over a period of 24 hours):
Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam /kg body weight (i.e. 0.4 ml/10 kg) before surgery, for example, at the time of induction of anaesthesia.

Cats:
Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery:
Single subcutaneous injection at a dosage of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg) before surgery, for example, at the time of induction of anaesthesia.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.
Avoid introduction of contamination during use.
Maximum number of piercings is 42 for all presentations.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the vial in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription**.**

14. Marketing authorisation numbers and pack sizes

EU/2/11/134/015 10 ml.
EU/2/11/134/016 20 ml.
EU/2/11/134/017 100 ml.

Pack sizes:
10, 20 and 100 ml injection vial.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

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For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Inflacam 5 mg/ml solution for injection for cattle and pigs

2. Composition

Each ml contains:

Active substance
Meloxicam 5 mg

Excipient
Ethanol (96 %) 159.8 mg

A clear, yellow solution.

3. Target species

Cattle (calves and young cattle) and pigs.

4. Indications for use

Cattle
For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For the relief of post-operative pain following dehorning in calves.

Pigs
For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For the relief of post-operative pain associated with minor soft tissue such as castration.

5. Contraindications

Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.
Do not use in pigs less than 2 days old.

6. Special warnings

Special precautions for safe use in the target species:
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Treatment of calves with Inflacam 20 minutes before dehorning reduces post-operative pain. Inflacam alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.
Treatment of piglets with Inflacam before castration reduces post-operative pain. To obtain pain relief during surgery co-medication with an appropriate anaesthetic/sedative is needed.
To obtain the best possible relieving effect post-surgery Inflacam should be administered 30 minutes before surgical intervention.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental self-injection may give rise to pain.
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Cattle: Can be used during pregnancy.
Pigs: Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

Overdose:
In case of overdose, symptomatic treatment should be initiated.

Major incompatibilities:
None known.

7. Adverse events

Cattle:

Common (more than 1 but less than 10 animals in 100 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[2].

[1]Slight and transient following subcutaneous administration
[2]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1].

[1]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Subcutaneous or intravenous use (cattle).
Intramuscular use (pigs).

Cattle
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 10 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs
Locomotor disorders:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2 ml/25 kg body weight). If required, a second administration of meloxicam can be given after 24 hours.

Reduction of post-operative pain:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 0.4 ml/5 kg body weight) before surgery.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.
Avoid introduction of contamination during use.

10. Withdrawal periods

Cattle: meat and offal: 15 days.
Pigs: meat and offal: 5 days.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/11/134/018 20 ml.
EU/2/11/134/019 50 ml.
EU/2/11/134/020 100 ml.

Pack sizes:
20, 50 and 100 ml injection vial.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

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Local representatives and contact details to report suspected adverse reactions:

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For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Inflacam 330 mg granules for horses

2. Composition

Each sachet contains:

Active substance
Meloxicam 330 mg

Pale yellow granules.

3. Target species

Horses.

4. Indications for use

Alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal disorders in horses weighing between 500 and 600 kg.

5. Contraindications

Do not use in pregnant or lactating mares.
Do not use in horses suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in horses less than 6 weeks of age.

6. Special warnings

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.
In order to minimise the risk of intolerance, the product should be mixed into muesli feed.
This product is only for use in horses weighing between 500 and 600 kg.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Laboratory studies in cattle have not provided any evidence of teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses. Therefore, do not use in pregnant or lactating mares.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticoids, other NSAIDs or with anti-coagulant agents.

Overdose:
In case of overdose, symptomatic treatment should be initiated.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, Lethargy Diarrhoea[1], Abdominal pain, Colitis. Urticaria[1,2],Anaphylactoid reactions[3].

[1]Reversible
[2]Slight
[3]May be serious (including fatal). If such reaction occurs, it should be treated symptomatically.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

In-feed use.

To be administered mixed with food at a dose of 0.6 mg/kg body weight, once daily, up to 14 days. The product should be added to 250 g of muesli feed, prior to feeding.

Each sachet contains one dose for a horse weighing between 500 kg and 600 kg and the dose must not be divided into smaller doses.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.
Avoid introduction of contamination during use.

10. Withdrawal periods

Meat and offal: 3 days.
Not authorised for use in animals producing milk for human consumption.

11. Special storage precautions

This veterinary medicinal product does not require any special storage conditions.

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and sachet after Exp. The expiry date refers to the last day of that month.

Shelf life after incorporation into muesli feed: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription**.**

14. Marketing authorisation numbers and pack sizes

EU/2/11/134/021 20 sachets.
EU/2/11/134/022 100 sachets.

Pack sizes:
20 and 100 sachets.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

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For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Inflacam 0.5 mg/ml oral suspension for cats

2. Composition

Each ml contains:

Active substance
Meloxicam 0.5 mg

Excipient
Sodium benzoate 1.5 mg

A smooth light yellow suspension.

3. Target species

Cats.

4. Indications for use

Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.
Alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats.

5. Contraindications

Do not use in pregnant or lactating animals.
Do not use in cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats less than 6 weeks of age.

6. Special warnings

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Post-operative pain and inflammation following surgical procedures:
In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders:
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation (see section "5 Contraindications").

Interaction with other medicinal products and other forms of interaction:
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Concurrent administration of potential nephrotoxic veterinary medicinal products should be avoided.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period should however take into account the pharmacological properties of the vetrinary medicinal products previously used.

Overdose:
Meloxicam has a narrow therapeutic safety margin in cats and clinical signs of overdose may be seen at relatively small overdose levels.
In case of overdose, adverse reactions, as listed in section "Adverse events", are expected to be more severe and more frequent. In case of overdose, symptomatic treatment should be initiated.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Appetite loss, Lethargy. Vomiting, Diarrhoea, Blood in faeces[1], Gastric ulcer, Small intestine ulcer, Large intestine ulcer. Elevated liver enzymes. Renal failure.

[1] occult

These side effects are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Oral use.

Post-operative pain and inflammation following surgical procedures:
After initial treatment with Inflacam 5 mg/ml solution for injection for cats, continue treatment 24 hours later with Inflacam 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight (0.1 ml/kg). The oral follow-up dose may be administered once daily (at 24-hour intervals) for up to 4 days.

Acute musculo-skeletal disorders:
Initial treatment is a single oral dose of 0.2 mg meloxicam/kg body weight (0.4 ml/kg) on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a dose of 0.05 mg meloxicam/kg body weight (0.1 ml/kg) for as long as acute pain and inflammation persist.

Chronic musculo-skeletal disorders:
Initial treatment is a single oral dose of 0.1 mg meloxicam/kg body weight (0.2 ml/kg) on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.05 mg meloxicam/kg body weight (0.1 ml/kg). A clinical response is normally seen within 7 days. Treatment should be discontinued after 14 days at the latest if no clinical improvement is apparent.

Route and method of administration
A one ml syringe is provided with the product. The precision of the syringe is not suitable for the treatment of cats below 1 kg.

Shake well before use. To be administered orally either mixed with food or directly into the mouth.

9. Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.
Avoid introduction of contamination during use.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging:
3 ml and 5 ml bottles: 14 days
10 ml and 15 ml bottles: 6 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription**.**

14. Marketing authorisation numbers and pack sizes

EU/2/11/134/023 10 ml.
EU/2/11/134/024 15 ml.
EU/2/11/134/025 3 ml.
EU/2/11/134/026 5 ml.

Pack sizes:
1 x 3 ml, 1 x 5 ml, 1 x 10 ml or 1 x 15 ml bottle with a measuring syringe.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Chanelle Pharmaceuticals Manufacturing Ltd.,
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Local representatives and contact details to report suspected adverse reactions:

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For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.