ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
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**
Benzyl alcohol	50 mg
Hydrochloric acid	
Meglumine	
Macrogol 400	
Macrogol 1500	
Sodium chloride	
Water for injections	

Clear, greenish 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 surgery 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 cases 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

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 effect post-surgery the veterinary medicinal product should be administered 30 minutes before surgical intervention.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 and pigs:

Common (1 to 10 animals / 100 animals treated):	Injection site pain[1], Injection site swelling[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactoid reaction[2]

[1] Transient
[2] May be serious (including fatal) and 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 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 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.
It is recommended to administer the second injection at a different site since local tolerance has been assessed after single injection only.

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.

Particular care should be taken with regard to the accuracy of dosing including the use of an appropriate dosing device and careful estimation of body weight.

Avoid introduction of contamination during use.

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

In the case of overdosage 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.
Not authorised for use in animals producing milk for human consumption.

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 properties. 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 µg/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 µg/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 biological 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

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

5.3 Special precautions for storage

Keep the injection vial in the outer carton in order to protect from light.
This veterinary medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 colourless, type I glass injection vial of 100 ml, which is closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

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

Dopharma Research B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/098/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 07/07/2009.

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

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

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
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	150 mg
Glycine	
Hydrochloric acid/sodium hydroxide	
Meglumine	
Macrogol 300	
Poloxamer 188	
Sodium citrate	
Water for injections	

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-metritisagalactia 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

See also section 3.7.
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 cases 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.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 (NSAID) 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, pigs and horses:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactoid reaction[2]

[1] Transient swelling following subcutaneous administration in cattle and intravenous administration in horses.
[2] May be serious (including fatal) and 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 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.

See also section 3.3.

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. 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).

Avoid introduction of contamination during use.

When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper. The maximum number of broachings should be limited to 20.

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

In the 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 B2 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 µg/ml and 2.7 µg/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 µg/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 biological 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

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: 28 days.

5.3 Special precautions for storage

Keep the injection vial in the outer carton in order to protect from light.
Do not refrigerate or freeze. Protect from frost.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 colourless, type I glass injection vial of 50 ml, 100 ml and 250 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

Dopharma Research B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/098/002
EU/2/09/098/003
EU/2/09/098/004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 07/07/2009.

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

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

Melovem 30 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Meloxicam 30 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	20 mg
Hydrochloric acid/sodium hydroxide	
Meglumine	
Macrogol 1500	
N-Methyl pyrrolidone	200 mg
Water for injections	

Clear yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

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 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-metritisagalactia syndrome) with appropriate antibiotic therapy.

3.3 Contraindications

See also section 3.7.
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 cases 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.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 (NSAID) 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.

Laboratory studies with the excipient N-methyl pyrrolidone have shown evidence of foetal malformations in rabbits and rats. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle and pigs:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactoid reaction[2]

[1] Transient swelling following subcutaneous administration in cattle.
[2] May be serious (including fatal) and 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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy, lactation and fertility:

The safety of the veterinary medicinal product has not been established in cattle and pigs during pregnancy and lactation or in animals intended for breeding. Laboratory studies with the excipient N-methyl pyrrolidone have shown evidence of foetal malformations in rabbits and rats. Use only according to the benefit-risk assessment by the responsible veterinarian.

See also section 3.3.

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 injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/150 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/150 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

Avoid introduction of contamination during use.

When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper. The maximum number of broachings should be limited to 20.

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

In the 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.

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 B2 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 µg/ml and 2.7 µg/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 µg/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.

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 biological 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

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: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Cardboard box with 1 colourless, type I glass injection vial of 50 ml, 100 ml and 250 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

Dopharma Research B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/098/005
EU/2/09/098/006
EU/2/09/098/007

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 07/07/2009.

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

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

Melovem 15 mg/ml oral suspension for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
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	1.5 mg
Sorbitol	
Glycerol	
Saccharin sodium	
Xylitol	
Silica, colloidal anhydrous	
Hydroxyethylcellulose	
Citric acid	
Honey aroma	
Water purified	

Yellow, aqueous 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 horses less than 6 weeks of age.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

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 animals 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.

This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

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):	Diarrhoea[1], appetite loss, lethargy, abdominal pain, colitis, urticaria Anaphylactoid reactions[2]

[1] Reversible
[2] May be serious (including fatal) and 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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Laboratory studies in cattle have not produced 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 glucocorticosteroids, 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 meloxicam/kg body weight (i.e. 4 ml/100 kg body weight), once daily, up to 14 days.

In case the 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. The syringe has a kg-body weight scale.

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 the 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, 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 B2 induced by *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 has not been 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: 6 months.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
After first opening, store below 25 °C.

5.4 Nature and composition of immediate packaging

White, rectangular high density polyethylene bottles of 250 ml or 500 ml of product with a narrow mouth opening, closed with a white polypropylene screw cap, and provided with a polypropylene transparent lid with space to include a polypropylene measuring syringe with a synthetic rubber piston.
Cardboard box with 1 white, round high-density polyethylene bottle of 100 ml of product closed with a white polypropylene screw cap and 1 polypropylene measuring syringe with a synthetic rubber piston.

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

Dopharma Research B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/09/098/008

EU/2/09/098/009
EU/2/09/098/010

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 07/07/2009.

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

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovem 5 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Cattle (calves and young cattle) and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: **s.c.**
Pigs: **i.m.**

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: Meat and offal: 15 days.
Not authorised for use in animals producing milk for human consumption.
Pigs: Meat and offal: 5 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached use by…

9. SPECIAL STORAGE PRECAUTIONS

Keep the injection vial in the outer carton in order to protect from light.

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

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/09/098/001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovem 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.**
Pigs: **i.m.**
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: Meat and offal: 15 days.
Not authorised for use in animals producing milk for human consumption.
Pigs: Meat and offal: 5 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached use by…

7. SPECIAL STORAGE PRECAUTIONS

Keep the injection vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovem 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. PACKAGE SIZE

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.**
Pigs: **i.m.**
Horses: **i.v.**

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: Meat and offal: 15 days; Milk: 5 days.
Pigs, horses: Meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached use by…

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.
Do not refrigerate or freeze. Protect from frost.

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

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/09/098/002 (50 ml)
EU/2/09/098/003 (100 ml)
EU/2/09/098/004 (250 ml)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass vial 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovem 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.**
Pigs: **i.m.**
Horses: **i.v.**
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: Meat and offal: 15 days; Milk: 5 days.
Pigs, horses: Meat and offal: 5 days.
Not authorised for use in horses producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached use by…

7. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.
Do not refrigerate or freeze. Protect from frost.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovem 20 mg/ml for cattle, pigs and horses

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached use by…

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovem 30 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 30 mg/ml

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: **s.c.**
Pigs: **i.m.**

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: Meat and offal: 15 days; Milk: 5 days.
Pigs: Meat and offal: 5 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached use 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

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/09/098/005 (50 ml)
EU/2/09/098/006 (100 ml)
EU/2/09/098/007 (250 ml)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass vial 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovem 30 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 30 mg/ml

3. TARGET SPECIES

Cattle and pigs

4. ROUTES OF ADMINISTRATION

Cattle: **s.c.**
Pigs: **i.m.**
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.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.
Once broached use by…

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovem 30 mg/ml for cattle and pigs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 30 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days
Once broached use by…

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box 100 ml
HDPE bottle 250 ml and 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovem 15 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 15 mg/ml

3. PACKAGE SIZE

100 ml
250 ml
500 ml

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
To be administered either mixed with food or directly into the mouth.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 6 months.
Once broached use by…

9. SPECIAL STORAGE PRECAUTIONS

After first opening, store below 25 °C.

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

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/09/098/008 (100 ml)
EU/2/09/098/009 (250 ml)
EU/2/09/098/010 (500 ml)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovem 15 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 15 mg/ml

3. TARGET SPECIES

Horses

4. ROUTES OF ADMINISTRATION

Oral use.
To be administered either mixed with food or directly into the mouth.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 6 months.
Once broached use by…

7. SPECIAL STORAGE PRECAUTIONS

After first opening, store below 25 °C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substances:
Meloxicam 5 mg

Excipients:
Benzyl alcohol 50 mg

Clear, greenish 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 surgery 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 cases 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 warnings:
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 effect post-surgery the veterinary medicinal product should be administered 30 minutes before surgical intervention.

Special precautions for safe use in the target species:
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 AntiInflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product. In case of accidental self-injection, seek medical advice immediately and show this 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 the case of overdosage, 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

Cattle and pigs:

Common (1 to 10 animals / 100 animals treated):	Injection site pain[1], Injection site swelling[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactoid reaction[2]

[1] Transient.
[2] May be serious (including fatal) and 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 its local representative 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

Cattle:

Single subcutaneous 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. It is recommended to administer the second injection at a different site since local tolerance has been assessed after single injection only.

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.
Particular care should be taken with regard to the accuracy of dosing including the use of an appropriate dosing device and careful estimation of body weight.

9. Advice on correct administration

Avoid introduction of contamination during use.

10. Withdrawal periods

Cattle: Meat and offal: 15 days.
Not authorised for use in animals producing milk for human consumption.

Pigs: Meat and offal: 5 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the injection vial in the outer carton in order to protect from light.

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

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

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.

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/2/09/098/001

Cardboard box with 1 vial of 100 ml.

15. Date on which the package leaflet was last revised

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 contact details to report suspected adverse events:
Dopharma Research B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer
Tel: +31-162-582000
pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:
Dopharma B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer

Local representative and contact details to report suspected adverse events:

België/Belgique/Belgien
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Detalhes de contacto para comunicar suspeitas de eventos adversos:
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PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substances:
Meloxicam 20 mg

Excipients:
Ethanol 150 mg

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 cases 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.

6. Special warnings

Special warnings:
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.

Special precautions for safe use in the target species:
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 AntiInflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product. In case of accidental self-injection, seek medical advice immediately and show this 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 the 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

Cattle, pigs and horses:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactoid reaction[2]

[1] Transient swelling following subcutaneous administration in cattle and intravenous administration in horses.
[2] May be serious (including fatal) and 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 its local representative 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

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).

9. Advice on correct administration

Avoid introduction of contamination during use.

When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper. The maximum number of broachings should be limited to 20.

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 animals producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the injection vial in the outer carton in order to protect from light.
Do not refrigerate or freeze. Protect from frost.
Shelf life after first opening the immediate packaging: 28 days.
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.

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/2/09/098/002
EU/2/09/098/003
EU/2/09/098/004

Cardboard box with 1 vial of 50 ml, 100 ml or 250 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 contact details to report suspected adverse events:
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PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Melovem 30 mg/ml solution for injection for cattle and pigs

2. Composition

Each ml contains:

Active substances:

Meloxicam	30 mg

Excipients:

Benzyl alcohol	20 mg
N-Methyl pyrrolidone	200 mg

Clear yellow solution.

3. Target species

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 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.

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 cases 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.

6. Special warnings

Special warnings:
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.

Special precautions for safe use in the target species:
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 AntiInflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product. In case of accidental self-injection, seek medical advice immediately and show this package leaflet or the label to the physician. Laboratory studies with the excipient N-methyl pyrrolidone have shown evidence of foetal malformations in rabbits and rats. Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

Pregnancy, lactation and fertility:
The safety of the veterinary medicinal product has not been established in cattle and pigs during pregnancy and lactation or in animals intended for breeding. Laboratory studies with the excipient N-methyl pyrrolidone have shown evidence of foetal malformations in rabbits and rats. Use only according to the benefit-risk assessment by the responsible veterinarian.

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 the 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

Cattle and pigs:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactoid reaction[2]

[1] Transient swelling following subcutaneous administration in cattle.
[2] May be serious (including fatal) and 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 its local representative 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

Cattle:
Single subcutaneous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/150 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/150 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

9. Advice on correct administration

Avoid introduction of contamination during use.

When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper. The maximum number of broachings should be limited to 20.

10. Withdrawal periods

Cattle:
Meat and offal: 15 days.
Milk: 5 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 temperature storage conditions.
Shelf life after first opening the immediate packaging: 28 days.
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.

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 pharamacist 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/2/09/098/005

EU/2/09/098/006
EU/2/09/098/007

Cardboard box with 1 vial of 50 ml, 100 ml or 250 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 contact details to report suspected adverse events:
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PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Melovem 15 mg/ml oral suspension for horses

2. Composition

Each ml contains:

Active substances:
Meloxicam 15 mg

Excipients:
Sodium benzoate 1.5 mg

Yellow, aqueous 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 horses less than 6 weeks of age.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animals 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.
This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

Pregnancy and lactation:

Laboratory studies in cattle have not produced 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.

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 the case of overdose symptomatic treatment should be initiated.

7. Adverse events

Horses:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Diarrhoea[1], appetite loss, lethargy, abdominal pain, colitis, urticaria (hives). Anaphylactoid reactions[2]

[1] Reversible.
[2] May be serious (including fatal) and 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 its local representative 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

To be administered either mixed with food or directly into the mouth at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 4 ml/100 kg body weight), once daily, up to 14 days.

9. Advice on correct administration

In case the 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. The syringe has a kg-body weight scale.
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.
Shake well before use.
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

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 label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months if stored below 25 °C.

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/2/09/098/008
EU/2/09/098/009
EU/2/09/098/010

Cardboard box with 1 bottle of 100 ml.
Bottle of 250 ml or 500 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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 contact details to report suspected adverse events:
Dopharma Research B.V.
Zalmweg 24
NL-4941 VX Raamsdonksveer
Tel: + 31-162-582000
pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:
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Zalmweg 24

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Local representative and contact details to report suspected adverse events:

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