

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdocam 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	150 mg
Poloxamer 188	
Macrogol 300	
Glycine	
Sodium hydroxide	
Hydrochloric acid	
Meglumine	
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 toxæmia (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 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 (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: (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

¹Following subcutaneous injection: slight and transient.

²May be serious (including fatal) and should be treated symptomatically

Pigs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactoid reaction ¹
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¹May be serious (including fatal) and should be treated symptomatically.

Horses:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactoid reaction ¹ Injection site swelling ²
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¹May be serious (including fatal) and should be treated symptomatically.

²Transient, observed in isolated cases in clinical studies.

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.

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 anticoagulant medicinal products.

3.9 Administration routes and dosage

For subcutaneous, intramuscular or intravenous use.

Cattle:

Single subcutaneous or intravenous injection at a dose 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 dose 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 dose 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, a suitable oral therapy containing meloxicam, administered in accordance with label recommendations, may be used for continuation of treatment.

Avoid introduction of contamination during use.

Do not breach the vial more than 50 times.

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

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 to 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 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: 3 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

Pack size of 1 colourless Type I glass vial containing 50 ml, 100 ml or 250 ml. Each vial is 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

Emdoka

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/128/001-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 18/08/2011

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) (<https://medicines.health.europa.eu/veterinary>).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdocam 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, liquid	
Glycerol	
Saccharin sodium	
Xylitol	
Sodium dihydrogen phosphate dihydrate	
Silica, colloidal anhydrous	
Xanthan gum	
Citric acid	
Honey aroma	
Purified water	

Yellow 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 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.

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):	Abdominal pain, colitis Appetite loss, lethargy Anaphylactoid reaction ¹
Undetermined frequency (Cannot be estimated from the available data):	Diarrhoea ² Urticaria

¹May be serious (including fatal) and should be treated symptomatically.

²Reversible.

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 provided any evidence for teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in 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 glucocorticoids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

3.9 Administration routes and dosage

For oral use.

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 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 fits onto the bottle and has volume scale and a “kg-body weight” scale which corresponds to the maintenance dose (i.e. 0.6 mg meloxicam / kg body weight).

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 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, 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 B₂ 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

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 first opening of 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

High density polyethylene bottle with a HDPE tamper-proof child-resistant screw cap and a 24 ml polypropylene measuring syringe with a volume scale and a “kg-body weight” scale which corresponds to the maintenance dose (i.e. 0.6 mg meloxicam / kg body weight).

Pack sizes:

Cardboard box with 1 bottle of 125 ml and a measuring syringe.

Cardboard box with 1 bottle of 336 ml and a 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

Emdoka

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/128/009 (125 ml)
EU/2/11/128/010 (336 ml)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 18/08/2011

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) (<https://medicines.health.europa.eu/veterinary>).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdocam 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
Ethanol	150 mg
Poloxamer 188	
Sodium chloride	
Glycine	
Hydrochloric acid	
Sodium hydroxide	
Glycofurol	
Meglumine	
Water for injections	

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 surgery such as castration.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Cattle:

Do not use in cattle suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

Pigs:

Do not use in pigs suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

Do not use in pigs less than 2 days old.

3.4 Special warnings

Cattle:

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 pain relief during surgery co-medication with an appropriate anaesthetic/sedative/analgesic is needed.

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

Pigs:

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/analgesic 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 severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.

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

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

Meloxicam may cause allergic reactions. People with known hypersensitivity to Non Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

Accidental self-injection may give rise to pain. In case of accidental self-injection, 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

Cattle (calves and young cattle):

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

¹Following subcutaneous injection: slight and transient.

²May be serious (including fatal) and should be treated symptomatically.

Pigs:

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

3.9 Administration routes and dosage

For subcutaneous, intramuscular or intravenous use.

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.

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.

As the vial should not be broached more than 50 times the user should select the most appropriate vial size according to the target species to be treated.

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 (calves and young 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 properties. 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). 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 in cattle and pigs.

In cattle and pigs, 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 metabolized to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

The main pathway of meloxicam biotransformation is oxidation.

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

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 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

Colourless type I glass vials closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

Pack sizes:

Cardboard box containing 1 vial of 50 ml.

Cardboard box containing 1 vial of 100 ml.

Cardboard box containing 1 vial of 250 ml.

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

Emdoka

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/128/004-006

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 18/08/2011

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) (<https://medicines.health.europa.eu/veterinary>).

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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
Ethanol	150 mg
Poloxamer 188	
Sodium chloride	
Glycine	
Hydrochloric acid	
Sodium hydroxide	
Glycofurol	
Meglumine	
Water for injections	

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 cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in dogs and cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.

Do not use in dogs and cats less than 6 weeks of age nor in cats of less than 2 kg.

3.4 Special warnings

None.

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 severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be 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:

Meloxicam may cause allergic reactions. People with known hypersensitivity to Non Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

Accidental self-injection may give rise to pain. In case of accidental self-injection, 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

Dogs, cats:

Rare (1 to 10 animals / 10 000 animals treated):	Appetite loss ¹ , lethargy ¹ Vomiting ¹ , diarrhoea ¹ , blood in faeces ^{1,2} Renal failure ¹
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Haemorrhagic diarrhoea ¹ , haematemesis ¹ , gastric ulcer ¹ , small intestine ulcer ¹ Elevated liver enzymes ¹ Anaphylactoid reaction ³

¹These adverse events 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.

²Occult.

³Should 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:

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 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, however, should take into account the pharmacological properties of the products used previously.

3.9 Administration routes and dosage

For subcutaneous or intravenous use.

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.

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).

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.

As the vial should not be broached more than 50 times the user should select the most appropriate vial size according to the target species to be treated.

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, anti-exudative, analgesic and antipyretic properties. 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 µg/ml in dogs and 1.1 µg/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 and cats. more than 97 % of meloxicam is bound to plasma proteins in dogs and cats.

The volume of distribution is 0.3 l/kg in dogs and 0.09 l/kg in cats.

Metabolism:

Meloxicam is predominantly found in plasma. It is also a major biliary excretion product in dogs and cats whereas urine contains only traces of the parent compound.

In cats five major metabolites were detected all having been shown to be pharmacologically inactive.

The main pathway of meloxicam biotransformation is oxidation.

Elimination:

In dogs and cats, 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 dogs.

In cats, 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: 3 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

Colourless type I glass vials closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

Pack sizes:

Cardboard box containing 1 vial of 20 ml.

Cardboard box containing 1 vial of 50 ml.

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

Emdoka

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/11/128/007-008

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 18/08/2011

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 \(https://medicines.health.europa.eu/veterinary\)](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

OUTER CARTON 50, 100 or 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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., i.v.
Pigs: i.m.
Horses: i.v.

7. 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.

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

Emdoka

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/128/001 50 ml
EU/2/11/128/002 100 ml
EU/2/11/128/003 250 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label 100 ml and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. TARGET SPECIES

Cattle, pigs and horses.

4. ROUTES OF ADMINISTRATION

Cattle: s.c., i.v.

Pigs: i.m.

Horses: i.v.

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 to 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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label for 50 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdocam 20 mg/ml solution for injection 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

Outer carton 125 ml and 336 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdocam 15 mg/ml oral suspension for horses

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 15 mg/ml

3. PACKAGE SIZE

125 ml
336 ml

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 3 days.
Not authorised for use in horses 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

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

Emdoka

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/128/009 125 ml

EU/2/11/128/010 336 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label 125 or 336 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Emdocam 15 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 15 mg/ml

3. TARGET SPECIES

Horses.

4. ROUTES OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 3 days.

Not authorised for use in horses 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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton 50 ml, 100 ml and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle (calves and young cattle) and pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: Single subcutaneous or intravenous injection.
Pigs: Single intramuscular injection.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle (calves and young cattle): Meat and offal: 15 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

Emdoka

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/128/004 50 ml
EU/2/11/128/005 100 ml
EU/2/11/128/006 250 ml

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label 100 ml and 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. TARGET SPECIES

Cattle (calves and young cattle) and pigs

4. ROUTES OF ADMINISTRATION

Cattle: Single subcutaneous or intravenous injection.

Pigs: Single intramuscular injection.

5. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle (calves and young cattle): Meat and offal: 15 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

Emdoka

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label 50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 5 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

Carton 20 ml and 50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. PACKAGE SIZE

20 ml
50 ml

4. TARGET SPECIES

Dogs, cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dogs: single intravenous or subcutaneous injection.
Cats: single subcutaneous injection.

7. WITHDRAWAL PERIODS

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

Emdoka

14. MARKETING AUTHORISATION NUMBERS

EU/2/11/128/007 20 ml

EU/2/11/128/008 50 ml

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label 20 ml and 50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

Once broached, use by...

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. 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 %)	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 toxemia (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 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:

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 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.

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 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 and 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 anticoagulant 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

Cattle:

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

¹Following subcutaneous injection: slight and transient.

²May be serious (including fatal) and should be treated symptomatically

Pigs:

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

¹May be serious (including fatal) and should be treated symptomatically.

Horses:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactoid reaction ¹ Injection site swelling ²
---	---

¹May be serious (including fatal) and should be treated symptomatically.

²Transient, observed in isolated cases in clinical studies.

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

For subcutaneous (**s.c.**), intramuscular (**i.m.**) or intravenous (**i.v.**) use.

Cattle

Single subcutaneous or intravenous injection at a dose 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 dose 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 dose 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, a suitable oral therapy containing meloxicam, administered in accordance with label recommendations, may be used for continuation of treatment.

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

9. Advice on correct administration

Avoid introduction of contamination during use.

Do not broach the vial more than 50 times.

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 to 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 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/2/11/128/001 (50 ml).
EU/2/11/128/002 (100 ml).
EU/2/11/128/003 (250 ml).

Pack size of 1 colourless Type I glass vial containing 50 ml, 100 ml or 250 ml. Each vial is closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
Emdoka
John Lijssenstraat 16
2321 Hoogstraten

Belgium
Tel. +32 (0) 3 315 04 26, info@emdoka.be

Manufacturer responsible for batch release:

Produlab Pharma bv.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse events:

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

België/Belgique/Belgien

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Lietuva

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PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Emdocam 15 mg/ml oral suspension for horses

2. Composition

Each ml contains:

Active substance:

Meloxicam 15.0 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

Yellow 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 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 warnings:

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 provided any evidence for teratogenic, foetotoxic, or maternotoxic effects. However, no data have been generated in horses. 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 anticoagulant 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

Horses:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Abdominal pain, colitis Appetite loss, lethargy Anaphylactoid reaction ¹
Undetermined frequency (Cannot be estimated from the available data):	Diarrhoea ² Urticaria (hives)

¹May be serious (including fatal) and should be treated symptomatically.

²Reversible.

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

For oral use.

Dosage

Oral suspension to be administered at a dosage of 0.6 mg/kg body weight, once daily, up to 14 days.

Method and route 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 volume scale and a “kg-body weight” scale which corresponds to the maintenance dose (i.e. 0.6 mg meloxicam / kg body weight).

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.

9. Advice on correct administration

Avoid introduction of contamination during use.

10. Withdrawal periods

Meat and offal: 3 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 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

EU/2/11/128/009 (125 ml).

EU/2/11/128/010 (336 ml).

Pack sizes:

Cardboard box with 1 bottle of 125 ml and a measuring syringe.

Cardboard box with 1 bottle of 336 ml and 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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder :

Emdoka
John Lijsenstraat 16
2321 Hoogstraten
Belgium
Tel. +32 (0) 3 315 04 26, info@emdoka.be

Manufacturer responsible for batch release:

Produlab Pharma bv,
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representatives and contact details to report suspected adverse events:

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

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Ísland

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Slovenská republika

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United Kingdom (Northern Ireland)

Duggan Veterinary Supplies Ltd.,
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Co Tipperary
Ireland
Tel: +353 (0) 504 43169

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. 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	150 mg

Clear yellow solution for injection.

3. Target species

Cattle and pigs.

4. Indications for use

Cattle (calves and young 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

Cattle:

Do not use in cattle suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

Pigs:

Do not use in pigs suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.

Do not use in pigs less than 2 days old.

6. Special warnings

Special warnings:

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

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

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

Special precautions for safe use in the target species:

Cattle:

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 pain relief during surgery co-medication with an appropriate anaesthetic/sedative/analgesic is needed.

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

Pigs:

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/analgesic 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 to be taken by the person administering the veterinary medicinal product to animals:

Meloxicam may cause allergic reactions. People with known hypersensitivity to Non Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

Accidental self-injection may give rise to pain. In case of accidental self-injection, 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:

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 anticoagulant 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

Cattle (calves and young cattle):

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

¹Following subcutaneous injection: slight and transient.

²May be serious (including fatal) and should be treated symptomatically.

Pigs:

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

For subcutaneous, intramuscular or intravenous use.

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 rehydration 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.

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.

As the vial should not be breached more than 50 times the user should select the most appropriate vial size according to the target species to be treated.

9. Advice on correct administration

Avoid introduction of contamination during use.

Do not breach the vial more than 50 times.

10. Withdrawal periods

Cattle (calves and young 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 label 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/2/11/128/004 (50 ml).

EU/2/11/128/004-005 (100 ml).

EU/2/11/128/004-006 (250 ml).

Pack sizes:

Cardboard box containing 1 vial of 50 ml.

Cardboard box containing 1 vial of 100 ml.

Cardboard box containing 1 vial of 250 ml.

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:

Emdoka
John Lijsenstraat 16
2321 Hoogstraten
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Tel. +32 (0) 3 315 04 26, info@emdoka.be

Manufacturer responsible for batch release:

Produlab Pharma bv
Forellenweg 16
4941 Raamsdonksveer
The Netherlands

Local representatives <and contact details to report suspected adverse events:

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

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United Kingdom (Northern Ireland)

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Tel: +353 (0) 504 43169

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. 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	150 mg

Clear yellow solution for injection.

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 cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in pregnant or lactating dogs and cats.

Do not use in dogs and cats suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders. Do not use in dog and cats less than 6 weeks of age nor in cats of less than 2 kg.

6. Special warnings

Special warnings:

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

Avoid use in any dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be 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:

Meloxicam may cause allergic reactions. People with known hypersensitivity to Non Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

Accidental self-injection may give rise to pain. In case of accidental self-injection, 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:

Do not use in pregnant or lactating dogs or cats.

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, however, should take into account the pharmacological properties of the products used previously.

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

Dogs, cats:

Rare (1 to 10 animals / 10 000 animals treated):	Appetite loss ¹ , lethargy ¹ Vomiting ¹ , diarrhoea ¹ , blood in faeces ^{1,2} Renal failure ¹
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Haemorrhagic diarrhoea ¹ , haematemesis (vomiting blood) ¹ , gastric ulcer ¹ , small intestine ulcer ¹ Elevated liver enzymes ¹ Anaphylactoid reaction ³

¹These adverse events 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.

²Occult.

³Should 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

For subcutaneous or intravenous use.

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).

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 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 body weight) before surgery, for example at the time of induction of anaesthesia.

As the vial should not be broached more than 50 times the user should select the most appropriate vial size according to the target species to be treated.

9. Advice on correct administration

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 label 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/2/11/128/007 (20 ml).

EU/2/11/128/008 (50 ml).

Pack sizes:

Cardboard box containing 1 vial of 20 ml.

Cardboard box containing 1 vial of 50 ml.

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) (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder :

Emdoka

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Belgium

Tel. +32 (0) 3 315 04 26, info@emdoka.be

Manufacturer responsible for batch release:

Produlab Pharma bv

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The Netherlands

Local representatives and contact details to report suspected adverse events:

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

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