[Version 9.1,11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosolute 5 mg/ml solution for injection for cattle, pigs, 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 (96 per cent) (E1510)	150 mg
Poloxamer 188	
Sodium chloride	
Glycine	
Hydrochloric acid	
Sodium hydroxide	
Glycofurol	
Meglumine	
Water for injection	

Clear, slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (calves and young cattle), pigs, dogs and cats

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.

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

3.3 Contraindications

Cattle and pigs
Do not use in animals suffering from impaired hepatic, cardiac or renal function or 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.
Do not use in pigs less than 2 days old.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

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

3.4 Special warnings

Cattle and pigs
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:

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

Dogs and Cats
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity. During anaesthesia, monitoring and fluid therapy should be considered as standard practice.

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

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.

This veterinary medicinal product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.
Meloxicam may be harmful for the foetus and unborn child. Pregnant women and women of child-bearing potential should not administer this product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle (calves and young cattle) and pigs:

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

[1] In cattle; slight and transient; following subcutaneous administration.
[2] May be serious (including fatal) and should be treated symptomatically.

Dogs and Cats:

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

[1] These 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.
[2] Occult
[3] 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

Cattle: Can be used during pregnancy.
Pigs: Can be used during pregnancy and lactation.
Dogs and cats: 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

Cattle and pigs
Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

Dogs and cats
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.

3.9 Administration routes and dosage

Cattle:
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 10.0 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. 2.0 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.

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

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

Cats:
Reduction of post-operative pain and inflammation when administration of meloxicam is to be continued as an oral follow-up therapy:
Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.04 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia. To continue treatment for up to five days, this initial dose may be followed 24 hours later by administration of meloxicam 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight. The oral follow-up dose may be administered for up to a total of four doses at 24 hour intervals.

Reduction of post-operative pain and inflammation where no oral follow-up treatment is possible e.g. feral cats:
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.
In this case do not use oral follow up treatment.

Particular care should be taken with regard to the accuracy of dosing. To ensure a correct dosage, body weight should be determined as accurately as possible. The use of an appropriate dosing device is recommended.

Avoid introduction of contamination during use.

The stopper should not be punctured more than 20 times.

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

In case of overdose symptomatic treatment should be initiated.

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

Not applicable.

3.12 Withdrawal periods

Cattle:	Meat and offal:	15 days
Pigs:	Meat and offal:	5 days

Not authorised for use in animals producing milk for human consumption, including non-lactating dairy cows during the dry period.

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. 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
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.
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
More than 97% of meloxicam is bound to plasma proteins.

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.
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range 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.
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.
In dogs and cats, meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound.
Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive. As for other species investigated, the main pathway of meloxicam biotransformation in cat 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.
In dogs, meloxicam is eliminated with a half-life of 24 hours. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.
In cats, meloxicam is eliminated with a half-life of 24 hours. The detection of metabolites from the parent compound in urine and faeces, but not in plasma is indicative for their rapid excretion. 21 % of the recovered dose is eliminated in urine (2 % as unchanged meloxicam, 19 % as metabolites) and 79 % in the faeces (49 % as unchanged meloxicam, 30 % as metabolites).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

Cardboard box containing one colourless glass (type I) injection vial of 10 ml, 20 ml or 100 ml, closed with a bromobutyl rubber stopper and sealed with an aluminium cap.
Not all pack sizes may be marketed.

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

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

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

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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 III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosolute 5 mg/ml solution for injection for cattle, pigs, dogs and cats

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. PACKAGE SIZE

10 ml
20 ml
100 ml

4. TARGET SPECIES

Cattle (calves and young cattle), pigs, dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: **s.c.** or **i.v.**
Pigs: **i.m.**
Dogs: **s.c.** or **i.v.**
Cats: **s.c.**

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: Meat and offal: 15 days
Pigs: Meat and offal: 5 days
Not authorised for use in animals producing milk for human consumption, including non-lactating dairy cows during the dry period.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

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

CP-Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass vial 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosolute 5 mg/ml solution for injection for cattle, pigs, dogs and cats

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

100 ml

3. TARGET SPECIES

Cattle (calves and young cattle), pigs, dogs and cats

4. ROUTES OF ADMINISTRATION

Cattle: **s.c.** or **i.v.**
Pigs: **i.m.**
Dogs: **s.c.** or **i.v.**
Cats: **s.c.**

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle: Meat and offal: 15 days
Pigs: Meat and offal: 5 days
Not authorised for use in animals producing milk for human consumption, including non-lactating dairy cows during the dry period.

6. EXPIRY DATE

Exp. {mm/yyyy}

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

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial 10 or 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosolute

cattle, pigs, dogs and cats

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

10 ml
20 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Melosolute 5 mg/ml solution for injection for cattle, pigs, dogs and cats

2. Composition

Each ml contains:

Active substances:

Meloxicam 5 mg

Excipients:

Ethanol (96 per cent) (E1510) 150 mg

Clear, slightly yellow solution.

3. Target species

Cattle (calves and young cattle), pigs, dogs and cats.

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.

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

5. Contraindications

Cattle and pigs
Do not use in animals suffering from impaired hepatic, cardiac or renal function or 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.
Do not use in pigs less than 2 days old.

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

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

6. Special warnings

Special warnings:

Cattle and pigs
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:

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

Dogs and Cats
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity. During anaesthesia, monitoring and fluid therapy should be considered as standard practice.

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

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.
This veterinary medicinal product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.
Meloxicam may be harmful for the foetus and unborn child. Pregnant women and women of child-bearing potential should not administer this product.

Pregnancy and lactation:

Cattle:	Can be used during pregnancy.
Pigs:	Can be used during pregnancy and lactation.
Dogs and cats:	The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Do not use in pregnant or lactating animals.

Interaction with other medicinal products and other forms of interaction:

Cattle and pigs
Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

Dogs and cats
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

Cattle (calves and young cattle) and pigs:

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

[1] In cattle; slight and transient; following subcutaneous administration.
[2] May be serious (including fatal) and should be treated symptomatically.

Dogs and Cats:

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

[1] These 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.
[2] Occult
[3] 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:

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

Cattle:
Single subcutaneous (**s.c.**) or intravenous (**i.v.**) injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 10.0 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:
Locomotor disorders:
Single intramuscular (**i.m.**) injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 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 (**i.m.**) injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 0.4 ml/5 kg body weight) before surgery.

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

Reduction of post-operative pain (over a period of 24 hours):
Single intravenous (**i.v.**) or subcutaneous (**s.c.**) 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 and inflammation when administration of meloxicam is to be continued as an oral follow-up therapy:
Single subcutaneous (**s.c.**) injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.04 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia. To continue treatment for up to five days, this initial dose may be followed 24 hours later by administration of meloxicam 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight. The oral follow-up dose may be administered for up to a total of four doses at 24 hour intervals.

Reduction of post-operative pain and inflammation where no oral follow-up treatment is possible e.g. feral cats:
Single subcutaneous (**s.c.**) 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.
In this case do not use oral follow up treatment.

The stopper should not be punctured more than 20 times.

9. Advice on correct administration

Particular care should be taken with regard to the accuracy of dosing. To ensure a correct dosage, body weight should be determined as accurately as possible. The use of an appropriate dosing device is recommended.
Avoid introduction of contamination during use.

10. Withdrawal periods

Cattle: Meat and offal: 15 days
Pigs: Meat and offal: 5 days

Not authorised for use in animals producing milk for human consumption, including non-lactating dairy cows during the dry period.

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: 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

Cardboard box with 1 vial of 10 ml, 20 ml or 100 ml.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

MM/YYYY

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release<and contact details to report suspected adverse events>:
CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
D-31303 Burgdorf
Germany

Local representatives and contact details to report suspected adverse events: