

## 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

One ml contains:

**Active substance:**

Meloxicam 5 mg

**Excipient:**

Ethanol 150 mg

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Solution for injection.

Clear, slightly yellow solution.

### 4 CLINICAL PARTICULARS

#### 4.1 Target Species

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

#### 4.2 Indications for use, specifying the 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.

**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:**

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

### 4.3 Contraindications

#### Cattle and pigs

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

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

#### Dogs and cats

Do not use in pregnant or lactating animals.

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

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

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

### 4.4 Special warnings for each target species

#### Cattle and pigs

Treatment of piglets with meloxicam 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 meloxicam should be administered 30 minutes before surgical intervention.

### 4.5 Special precautions for use

#### Special precautions for use in animals

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.

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

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

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

Accidental self-injection may give rise to pain. People with known hypersensitivity to Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Meloxicam may be harmful for the foetus and unborn child. Pregnant women and women of child-bearing potential should not administer this product.

## 4.6 Adverse reactions (frequency and seriousness)

### Cattle and pigs

Subcutaneous, intramuscular as well as intravenous administration is well tolerated; only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10% of the cattle treated in clinical studies.

In very rare cases anaphylactoid reactions which may be serious (including fatal) may occur and should be treated symptomatically.

### Dogs and cats

Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have occasionally been reported. In very rare cases elevated liver enzymes have been reported.

In dogs, in very rare cases, haemorrhagic diarrhoea, haematemesis, and gastrointestinal ulceration have been reported. In dogs, these side effects occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

In very rare cases anaphylactoid reactions may occur and should be treated symptomatically.

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

## 4.7 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 (See section 4.3).

## 4.8 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. Meloxicam 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.

## 4.9 Amounts to be administered and administration route

### 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.

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

#### Reduction of post-operative pain (over a period of 24 hours):

Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight) before surgery, for example at the time of induction of anaesthesia.

### Cats:

#### Reduction of post-operative pain:

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

Particular care should be taken with regard to the accuracy of dosing.

Avoid introduction of contamination during use.

The stopper should not be punctured more than 20 times.

## 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of overdose symptomatic treatment should be initiated.

## 4.11 Withdrawal Period(s)

**Cattle:** Meat and offal: 15 days

**Pigs:** Meat and offal: 5 days

Do not use in cattle producing milk for human consumption, including non-lactating dairy cows during the dry period.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids (oxicams)

ATCvet code: QM01AC06

## 5.1 Pharmacodynamic properties

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 B<sub>2</sub> 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).

## 5.2 Pharmacokinetic properties

### 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).

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Ethanol

Poloxamer 188

Sodium chloride

Glycine

Hydrochloric acid

Sodium hydroxide

Glycofurol

Meglumine

Water for injection

### **6.2 Incompatibilities**

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

### **6.3 Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 36 months

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

### **6.4 Special precautions for storage**

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

### **6.5 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.

### **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## **7 MARKETING AUTHORISATION HOLDER**

CP-Pharma Handelsgesellschaft mbH

Ostlandring 13

D-31303 Burgdorf

Germany

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA: 10810/009/001

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

19th October 2012

**10 DATE OF REVISION OF THE TEXT**

January 2014