# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosolute 40 mg/ml solution for injection for cattle and horses.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains:

Active substance:
Meloxicam 40 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 and horses.

### 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.
For adjunctive therapy in the treatment of acute mastitis, in combination with 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.

### 4.3 Contraindications

See also section 4.7.
Do not use in horses less than 6 weeks of age.
Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in 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.

## 4.4 Special warnings for each target species

None.

## 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.
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.
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)

In cattle intravenous administration is well tolerated.

In horses, a transient swelling at the injection site can occur but resolves without intervention.

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

## 4.7 Use during pregnancy, lactation or lay

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

See also section 4.3.

## 4.8 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.

## 4.9 Amounts to be administered and administration route

**Cattle:**
Single intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 1.25 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

**Horses:**
Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 1.5 ml/100 kg body weight).

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

## 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 effects. It reduces leukocyte infiltration into the inflamed tissue. To a minor extent it also inhibits collagen-induced thrombocyte aggregation. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B2 induced by *E. coli* endotoxin administration in calves and, lactating cows.

## 5.2 Pharmacokinetic properties

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. 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
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.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

- Ethanol
- Poloxamer 188
- Macrogol 300
- Glycine
- Disodium edetate
- Sodium hydroxide
- Hydrochloric acid
- 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: 24 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 50 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 10810/009/003

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

14th June 2013

## 10 DATE OF REVISION OF THE TEXT