SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animeloxan, 5 mg/ml, solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution for injection contains
Active substance:
Meloxicam 5 mg
Excipients:
Ethanol, anhydrous 110.60 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for Injection
Clear, yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Dog, cat

4.2 Indications for use, specifying the 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.

4.3 Contraindications

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

For post-operative pain relief in cats, safety has only been documented after thiopental/halothane anaesthesia.

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 any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.
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
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.
If accidental skin contact occurs, wash the affected area thoroughly. Wash hands after use.
In view of the risk of accidental self-injection and the known adverse class-effects of NSAIDs and other prostaglandin inhibitors on pregnancy and/or embryofoetal development, the veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.

4.6 Adverse reactions (frequency and seriousness)

Typical adverse drug reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, apathy and renal failure have occasionally 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.
Injection site pain.

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant or lactating animals. The safety of the veterinary medicinal product has not been established during pregnancy and lactation (See 4.3).

4.8 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. Animeloxan 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 drugs

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

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).
Animeloxan 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.

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

In the case of overdosage symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL 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, 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. 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 particulars

Absorption
In cats, maximum plasma concentrations of meloxicam were reached at 3.2 h post single subcutaneous injection of *Animeloxan 5 mg/ml* at a dose of 0.3 mg meloxicam/kg body weight.

In dogs, maximum plasma concentrations of meloxicam were reached at 3.1 h post single subeutaneous administration of *Animeloxan 5 mg/ml* at a dose of 0.2 mg meloxieam/kg body weight.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range in dogs. More than 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg in dogs and 0.09 l/kg in cats.

Metabolism
In dogs, 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.

Elimination
In cats, the mean terminal half-life was calculated to be 18.8 h.
In dogs, the mean terminal half-life was calculated to be 20.0 h.
Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

N-Methylpyrrolidone
Ethanol, anhydrous
Sodium hydroxide (for pH-adjustment)
Hydrochloric acid, dilute (for pH-adjustment)
Water for injections

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: 3 years.
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 temperature storage conditions.

6.5 Nature and composition of immediate packaging

Clear glass (type I) bottles of 10 ml, 20 ml and 25 ml, each closed with bromobutyl rubber stoppers and fixed with Aluminium/PP flip caps.
Available in cardboard cartons containing:
1 x 10 ml or 5 x 10 ml
1 x 20 ml or 5 x 20 ml
1 x 25 ml or 5 x 25 ml.
Not all pack sizes may be marketed.

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

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

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT

December 2017

Approved: 06 December 2017