Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Animeloxan, 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:

Ethanol, anhydrous	158.00 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

Cattle, pigs and horses.

4.2 Indications for use, specifying the target species

Cattle:
Single subcutaneous or intravenous use at a dosage 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 use at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 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. Alternating injection sites are recommended.

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 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.

4.4 Special warnings for each target species

Treatment of calves with Animeloxan 20 minutes before dehorning reduces post-operative pain. Animeloxan 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.

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.
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)

In cattle, a single subcutaneous injection can cause a non-painful swelling that lasts up to 23 days. Intravenous injection is generally well-tolerated.

In pigs, two consecutive intramuscular injections have a local irritant effect that can last up to 9 days.

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

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

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Cattle and pigs:
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 interactions

Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anti-coagulant agents.

4.9 Amounts to be administered and administration route

Cattle:
Single subcutaneous or intravenous use at a dosage 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 use at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 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. Alternating injection sites are recommended.

Horses:
Single intravenous use at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3.0 ml/100 kg body weight).

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

In the case of overdosage symptomatic treatment should be initiated.

4.11 Withdrawal period(s)

Cattle:

Meat and offal:	15 days
Milk:	5 days

Pigs:

Meat and offal:	8 days

Horses:

Meat and offal:	5 days

Do not use in horses producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group:	Anti-inflammatory and antirheumatic products, non-steroids (oxicams)
ATCvet code:	QM01AC0

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. Meloxicam also has anti-endotoxic properties because it has been shown to inhibit production of thromboxane B_2 induced by E. coli endotoxin administration in calves, lactating cows and pigs.

5.2 Pharmacokinetic particulars

Absorption
In pigs, maximum plasma concentrations of meloxicam were reached at 1.0 h post administration of single intramuscular administration of Animeloxan 20 mg/ml at a dose of 0.4 mg meloxicam/kg body weight.

In cattle, maximum plasma concentrations of meloxicam were reached at 6.8 h post single subcutaneous administration of *Animeloxan 20 mg/ml* at a dose of 0.5 mg meloxicam/kg body weight.

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
In pigs, the mean terminal half-life was calculated to be approximately 3.2 h for meloxicam following intramuscular administration.

In cattle, the mean terminal half-life following subcutaneous administration was calculated to be approximately 14.0 h for meloxicam.

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

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

6.2 Major 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 theveterinary medicinal product as packaged for sale: 3 years.
Shelf-life afterfirst 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 50 ml and 100 ml, each closed with bromobutyl rubber stoppers and fixed with Aluminium caps or Aluminium/PP flip caps.
Available in cardboard boxes containing:
1 x 50 ml or 12 x 50 ml
1 x 100 ml or 12 x 100 ml
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10826/025/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 May 2019

10 DATE OF REVISION OF THE TEXT

August 2019