

ANNEX I
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:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
N-Methylpyrrolidone	718.20 mg
Ethanol, anhydrous	158.00 mg
Sodium hydroxide (for pH-adjustment)	
Hydrochloric acid, dilute (for pH-adjustment)	
Water for injections	

Clear, yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs and horses.

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

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 adjunctive therapy in the treatment of puerperal septicaemia and toxæmia (mastitis-metritis-agalactia syndrome) with appropriate 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.

3.3 Contraindications

See also section 3.7.

Do not use in horses less than 6 weeks of age.

Do not use in cases of 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.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

NSAIDs and other prostaglandin inhibitors are known to have adverse effects on pregnancy and/or embryofoetal development.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects.

Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactoid reaction ¹
Undetermined frequency (cannot be estimated from the available data):	Injection site swelling ²

Pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactoid reaction ¹
Undetermined frequency (cannot be estimated from the available data):	Injection site irritation ³

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactoid reaction ¹
Undetermined frequency (cannot be estimated from the available data):	Injection site swelling ⁴

¹ May be serious (including fatal); should be treated symptomatically.

² After single subcutaneous injection; non-painful; can last up to 23 days.

³ After two consecutive intramuscular injections; can last up to 9 days.

⁴ Transient; resolves without intervention.

If adverse events 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 layPregnancy and lactation:

Cattle and pigs:

The safety of the veterinary medicinal product has not been established in cattle and pigs during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Horses:

Do not use in pregnant or lactating mares.

See also section 3.3.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Intravenous, subcutaneous or intramuscular use.

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).

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

In the case of overdosage, 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

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.

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, 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 B2 induced by *E. coli* endotoxin administration in calves, lactating cows and pigs.

4.3 Pharmacokinetics**Absorption**

In pigs, maximum plasma concentrations of meloxicam were reached at 1.0 h post administration of single intramuscular administration of the veterinary medicinal product 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 the veterinary medicinal product 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.

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 temperature storage conditions.

5.4 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 in a cardboard box.

Pack sizes:

1 x 50 ml
12 x 50 ml
1 x 100 ml

12 x 100 ml

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

aniMedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

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) (<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

Animeloxan, 20 mg/ml, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Meloxicam 20 mg

3. PACKAGE SIZE

50 ml

100 ml

12 x 50 ml

12 x 100 ml

4. TARGET SPECIES

Cattle, pigs and horses.

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

Cattle: s.c., i.v.

Pigs: i.m.

Horses: i.v.

7. WITHDRAWAL PERIODS

Withdrawal period:

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.

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”
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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

aniMedica GmbH

14. MARKETING AUTHORISATION NUMBERS
--

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label 100 ml, 50 ml bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animeloxan, 20 mg/ml, solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Meloxicam 20 mg

3. TARGET SPECIES

Cattle, pigs and horses.

4. ROUTES OF ADMINISTRATION

Cattle: s.c., i.v.

Pigs: i.m.

Horses: i.v.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

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.

6. EXPIRY DATE

Exp. {mm/yyyy} Once broached, use within 28 days.

Once opened, use by:

7. SPECIAL STORAGE PRECAUTIONS**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

aniMedica GmbH

9. BATCH NUMBER

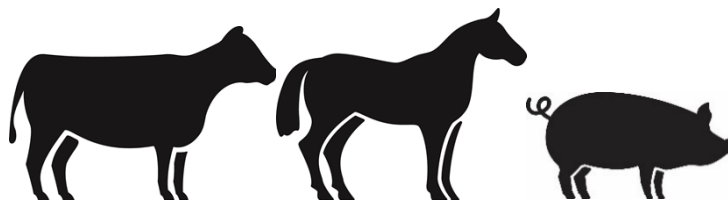
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label 50 ml bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animeloxan

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Meloxicam

20 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy} Once broached, use within 28 days.

Once opened, use by:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Animeloxan, 20 mg/ml, solution for injection for cattle, pigs and horses

2. Composition

Each ml contains:

Active substance:

Meloxicam	20 mg
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Excipients:

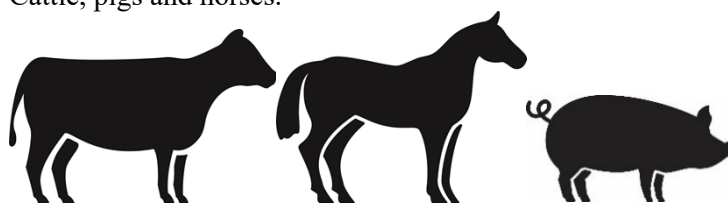
N-Methylpyrrolidone	718.20 mg
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Ethanol, anhydrous	158.00 mg
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Clear, yellow solution.

3. Target species

Cattle, pigs and horses.



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

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 adjunctive therapy in the treatment of puerperal septicaemia and toxemia (mastitis-metritis-agalactia syndrome) with appropriate 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.

5. Contraindications

See also section “Pregnancy and lactation”.

Do not use in horses less than 6 weeks of age.

Do not use in cases of 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.

6. Special warnings

Special warnings:

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.

Special precautions for safe use in the target species:

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.

NSAIDs and other prostaglandin inhibitors are known to have adverse effects on pregnancy and/or embryofoetal development.

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects.

Women of childbearing age, pregnant women or women suspected of being pregnant should use the veterinary medicinal product with serious caution to avoid accidental self-injection.

Pregnancy and lactation:

Cattle and pigs:

The safety of the veterinary medicinal product has not been established in cattle and pigs during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

Horses:

Do not use in pregnant or lactating mares.

See also section "Contraindications".

Interaction with other medicinal products and other forms of interaction:

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

Overdose:

In the case of overdosage, 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:

Rare (1 to 10 animals / 10,000 animals treated): Anaphylactoid reaction (severe allergic reaction)¹

Undetermined frequency (cannot be estimated from the available data): Injection site swelling²

Pigs:

Rare (1 to 10 animals / 10,000 animals treated): Anaphylactoid reaction (severe allergic reaction)¹

Undetermined frequency (cannot be estimated from the available data): Injection site irritation³

Horses:

Rare (1 to 10 animals / 10,000 animals treated): Anaphylactoid reaction (severe allergic reaction)¹

Undetermined frequency (cannot be estimated from the available data): Injection site swelling⁴

¹ May be serious (including fatal); should be treated symptomatically.

² After single subcutaneous injection; non-painful; can last up to 23 days.

³ After two consecutive intramuscular injections; can last up to 9 days.

⁴ Transient; resolves without intervention.

If adverse events 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 the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: <{national system details}>.

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

Intravenous, subcutaneous or intramuscular use.

Cattle:

Single subcutaneous (s.c.) or intravenous (i.v.) 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 (i.m.) 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).

9. Advice on correct administration

None.

10. Withdrawal periods

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.

11. Special storage precautions

Keep out of the sight and reach of children.

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

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

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after Exp. The expiry date refers to the last date of that month.

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

Pack sizes:

1 x 50 ml glass vial in a cardboard box.

12 x 50 ml glass vial in a cardboard box.

1 x 100 ml glass vial in a cardboard box.

12 x 100 ml glass vial in a cardboard box.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany
Tel: +49-2536-3302-0

Manufacturer responsible for batch release:

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industrial Veterinaria, S.A.
Esmeralda 19
08950 Esplugues de Llobregat (Barcelona)

Spain

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Local representatives and contact details to report suspected adverse reactions: