

**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”**

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**

Vm 24745/4015

**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}



**PARTICULARS TO APPEAR ON THE 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

**Excipients:**

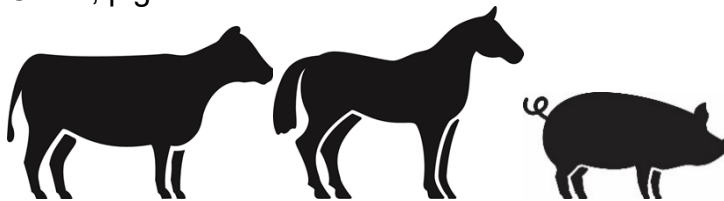
N-Methylpyrrolidone 718.20 mg

Ethanol, anhydrous 158.00 mg

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)<sup>1</sup>

Undetermined frequency (cannot be estimated from the available data): Injection site swelling<sup>2</sup>

Pigs:

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

Undetermined frequency (cannot be estimated from the available data): Injection site irritation<sup>3</sup>

Horses:

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

Undetermined frequency (cannot be estimated from the available data): Injection site swelling<sup>4</sup>

<sup>1</sup> May be serious (including fatal); should be treated symptomatically.

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

<sup>3</sup> After two consecutive intramuscular injections; can last up to 9 days.

<sup>4</sup> 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 at <https://www.gov.uk/report-veterinary-medicine-problem>.

## **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.

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**

Vm 24745/4015

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. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

## **16. Contact details**

Marketing authorisation holder:

aniMedica GmbH  
Im Südfeld 9  
48308 Senden-Bösensell  
Germany

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 representative and contact details to report suspected adverse reactions:

FORTE Healthcare Limited,  
Block 3, Unit 9,  
CityNorth Business Campus,  
Stamullen, Co.  
Meath. K32 D990  
Republic of Ireland  
Tel.: +353 1 841 7666  
E-Mail: [pharmacovigilance@fortehealthcare.com](mailto:pharmacovigilance@fortehealthcare.com)

## **17. Other information**

POM-V - Veterinary medicinal product subject to prescription

Approved 14 March 2025

*Gavin Hall*