MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Label 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

20 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle:
For subcutaneous or intravenous use.

Pigs:
For intramuscular use.

Horses:
For intravenous use.

5. WITHDRAWAL PERIOD

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. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP:
Once broached, use by 28 days.
Once opened, use by:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

ADDITIONAL

aniMedica GmbH, Im Südfeld 9, D-48308 Senden-Bösensell

IE: Distributor: FORTE Healthcare Ltd., Cougar Lane, Naul,Co. Dublin Ireland

<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains

Active substance:
Meloxicam 20 mg

Excipients:
Ethanol, anhydrous 158.00 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle:
For subcutaneous or intravenous use.

Pigs:
For intramuscular use.

Horses:
For intravenous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by 28 days.
Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 24745/4015

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Meloxicam 20 mg

Excipients:
Ethanol, anhydrous 158.00 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml, 100 ml, 12 x 50 ml, 12 x 100 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle:
For subcutaneous or intravenous use.

Pigs:
For intramuscular use.

Horses:
For intravenous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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.

9. SPECIAL WARNING(S), IF NECESSARY

The veterinary medicinal product should not be administered by pregnant women or women attempting to conceive. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by 28 days.
Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 24745/4015

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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
Esplugues de LLobregat
08950 Barcelona
Spain

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains

Active substance:

Meloxicam	20 mg

Excipients:

N-Methylpyrrolidone	718.20 mg
Ethanol, anhydrous	158.00 mg

Solution for injection
Clear, yellow solution.

4. INDICATION(S)

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 toxaemia (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

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.

6. ADVERSE REACTIONS

I
n 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.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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).

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, pigs and horses

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Solution for injection.

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).

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 container 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.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Special warninngs 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.

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.
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.

Use during pregnancy, lactation or lay

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.

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 (symptoms, emergency procedures, antidotes), if necessary
In the case of overdosage, symptomatic treatment should be initiated.

Incompatibilities
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

For animal treatment only - to be supplied only on veterinary prescription.

Vm: 24745/4015 POM-V

Approved 21 September 2023