PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animeloxan 1.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Meloxicam 1.5 mg

Excipient:
Sodium benzoate 1.5 mg

3. PACKAGE SIZE

10 ml bottle
25 ml bottle
50 ml bottle
100 ml bottle
125 ml bottle

A measuring device (a plastic syringe) is also included in the pack.

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Shake well before use.
To be administered mixed with food or directly into the mouth.
Read the package leaflet before use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf-life after first opening the immediate packaging: 6 months
Once opened, use by: ……..

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

{Name or company name or logo name of the marketing authorisation holder}

Distributor:
FORTE Healthcare Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 24745/5000

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V (‘Veterinary medicinal product subject to prescription’)

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {100 ml, 125 ml – via adhesive label on bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animeloxan 1.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:
Meloxicam 1.5 mg

Excipient:
Sodium benzoate 1.5 mg

3. TARGET SPECIES

Dogs

(a pictogram may be used to replace the wording)

4. ROUTES OF ADMINISTRATION

Shake well before use.
To be administered mixed with food or directly into the mouth.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyyy}

Shelf-life after first opening the immediate packaging: 6 months
Once opened, use by: …….

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

{Name or company name or logo name of the marketing authorisation holder}

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V ('Veterinary medicinal product subject to prescription')

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {10 ml, 25 ml, 50 ml via adhesive label on bottle}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animeloxan

Dogs

(a pictogram may be used to replace the wording)

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Shelf-life after first opening the immediate packaging: 6 months
Once opened, use by: ……

5. ROUTE(S) OF ADMINISTRATION

Shake well before use.
To be administered mixed with food or directly into the mouth.
Read the package leaflet before use.

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Animeloxan 1.5 mg/ml oral suspension for dogs

2. COMPOSITION

Each ml contains:

Active substance:

Meloxicam 1.5 mg

Excipient:

Sodium benzoate 1.5 mg

Pale yellow viscous suspension.

3. TARGET SPECIES

Dogs

4. INDICATIONS FOR USE

Meloxicam is a Non Steroidal Anti-Inflammatory Drug (NSAID) that alleviates inflammation and pain in both acute and chronic musculo-skeletal disorders.

5. CONTRAINDICATIONS

- Do not use in pregnant or lactating animals.
- 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 cases of hypersensitivity to the active substance or to any of the excipients.
- Do not use in dogs less than 6 weeks of age.

6. SPECIAL WARNING(S)

For Animal Treatment Only

Special precautions for safe use in the target species:

If side effects 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 increased renal toxicity.

In case of prolonged use, monitoring during treatment should be carried out.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy:
Do not use during pregnancy.

Lactation:
Do not use for nursing bitches.

Interaction with other medicinal products and or other form of interaction:
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Meloxicam must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

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 pharmacokinetic properties of the veterinary medicinal products used previously.

Meloxicam may antagonise the antihypertensive effects of ACE inhibitors.

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

Dog:

Undetermined frequency (cannot be estimated from the available data): Appetite loss[1], vomiting[1], diarrhoea[1], blood in faeces[1,2], apathy[1]

[1]These typical adverse drug reactions of NSAIDs occur occasionally and 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.

[2]occult

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 using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

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

Shake well before use.
To be administered mixed with food or directly into the mouth.

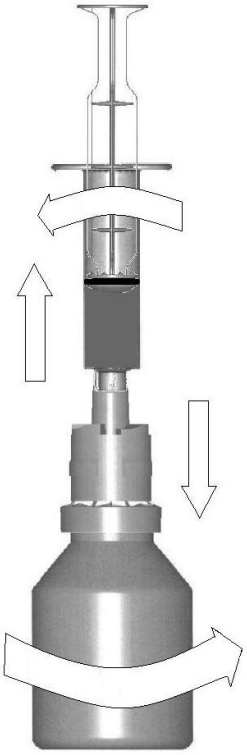
Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight (equivalent to 0,07 ml/kg).

Particular care should be taken with regard to the accuracy of dosing.

The suspension can be given using the measuring syringe provided in the package. The syringe provided allows dosing for dogs with a body weight of 2.5 – 45 kg. For dosing dogs with a body weight of less than 2.5 kg, a syringe with a smaller volume (0.5 ml, 1 ml) must be used. The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg body weight corresponds to 0,07 ml/kg bodyweight). Thus for the first day, twice the maintenance volume will be required.

Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end onto the top of the bottle.

Turn the bottle/syringe upside down. Pull the plunger out until the line on the plunger corresponds to your dog's bodyweight in kilograms



Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle

Empty the contents of the syringe onto the food by pushing the plunger in or directly into the mouth.

A clinical response is normally seen within 3 - 4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose of the veterinary medicinal product can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

Avoid introduction of contamination during use.

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.

The date of first use (on first opening of the bottle) should be recorded on the space provided on the label or carton, along with the expiry date of the opened bottle (six months from the date of opening). Any unused veterinary medicinal product should be discarded after this date.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.

After each dose, the tip of the syringe should be wiped and the bottle cap screwed back on tightly. The syringe should be stored in the carton box in between uses.

Shelf-life after first opening the immediate packaging: 6 months.

Do not use after the expiry date stated on the carton and the bottle.
The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 24745/5000

10 ml, 25 ml, 50 ml, 100 ml or 125 ml bottle.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

August 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Local representatives 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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. OTHER INFORMATION

POM-V ('Veterinary medicinal product subject to prescription')

Distributor
FORTE Healthcare Limited,
Block 3, Unit 9,
CityNorth Business Campus,
Stamullen, Co.
Meath. K32 D990
Republic of Ireland

Approved 23 January 2024