

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Outer carton
Vials of 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Single subcutaneous or intravenous injection

Pigs: Single intramuscular injection. If required, a second administration can be given after 24 hours.

Horses: Single intravenous injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal: 15 days, Milk: 120 hours
Pigs: Meat and offal: 5 days

Horses: Meat and offal: 5 days

Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Pregnant women and women of childbearing age should exercise caution when handling this product. **Read package leaflet before use.**

10. EXPIRY DATE

EXP {month/year}

Once broached use within 28 days.

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

Alfasan Nederland B.V
Kuipersweg 9
3449 JA Woerden
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 36408/3008

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vials of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 20 mg/ml

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC or IV

Pigs: IM

Horses: IV

5. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal: 15 days, Milk: 120 hours

Pigs: Meat and offal: 5 days

Horses: Meat and offal: 5 days

Not authorised for use in horses producing milk for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

Once broached use within 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Metaxx 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:

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Manufacturer responsible for batch release:

Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

or

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Meloxicam

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

One ml contains:

Active substance:

Meloxicam 20 mg

Excipients:

Ethanol anhydrous (E1510) 150 mg

Clear yellow solution for injection.

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 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.

5. CONTRAINDICATIONS

See also section “Special Warnings – Pregnancy”

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

In cattle, only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.

In horses, a transient swelling at the injection site was observed in isolated cases in clinical studies, but resolved without intervention.

Anaphylactoid reactions, which may be serious (including fatal), have been observed very rarely from post-marketing safety experience 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).

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

Cattle:

Single subcutaneous or intravenous injection 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 injection 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.

Horses:

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

For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo- skeletal disorders, a suitable oral therapy containing meloxicam, administered in accordance with label recommendations, may be used for continuation of treatment, 24 hours after administration of the injection.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.
The stopper may not be punctured more than 50 times.

10. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal: 15 days, Milk: 120 hours

Pigs: Meat and offal: 5 days

Horses: Meat and offal: 5 days

Not authorised for 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 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 carton and vial after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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 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. Meloxicam and other non-steroidal anti-inflammatory drugs (NSAIDs) may cause hypersensitivity (allergic reactions).

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.

This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

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, this product should not be administered by pregnant women or women attempting to conceive.

Pregnancy and lactation:

Cattle and pigs: Can be used during pregnancy and lactation.

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 anticoagulant agents.

Overdose (symptoms, emergency procedures, antidotes):

In case of overdose, symptomatic treatment should be initiated.

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

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Colourless glass (Type I) injection vial closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

Cardboard box of 1 vial of 50 ml

Cardboard box of 1 vial of 100 ml

Cardboard box of 1 vial of 250 ml

Not all pack sizes may be marketed.

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

Approved 09 November 2022

