

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosolute 40 mg/ml solution for injection for cattle and horses
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 40 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Cattle and horses

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: IV
Horses: IV

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle: meat and offal: 15 days; milk: 5 days

Horses: meat and offal: 5 days.

Not authorised to 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}
Shelf-life of broached vial: 28 days.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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

Read the package leaflet before use.

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 REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
D-31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosolute 40 mg/ml solution for injection for cattle and horses
Meloxicam

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 40 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Cattle and horses

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: IV
Horses: IV

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle: meat and offal: 15 days; milk: 5 days

Horses: meat and offal: 5 days.

Not authorised to 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}
Shelf-life of broached vial: 28 days.
Once broached, use by...

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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

Read the package leaflet before use.

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

For animal treatment only

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH
Germany

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Melosolute 40 mg/ml solution for injection for cattle and horses

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

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
D-31303 Burgdorf
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melosolute 40 mg/ml solution for injection for cattle and horses
Meloxicam

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

One ml contains:

Meloxicam	40 mg
Ethanol	150 mg

Clear, slightly 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.

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 pregnant or lactating mares.

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 case 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 intravenous administration is well tolerated.

In horses, a transient swelling at the injection site can occur but resolves without intervention.

In very rare cases anaphylactoid reactions which may be serious (including fatal) may occur and should be treated symptomatically.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle and horses.

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

Cattle:

Single intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 1.25 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Horses:

Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 1.5 ml/100 kg body weight).

The stopper should not be punctured more than 20 times.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD

Cattle: meat and offal: 15 days; milk: 5 days

Horses: meat and offal: 5 days

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight 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 after the expiry date stated on the carton and vial after EXP.

12. SPECIAL WARNING(S)

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.

Precautions to be taken by the person administering the product

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 this package leaflet or the label to the physician.

Meloxicam may be harmful for the foetus and unborn child. Pregnant women and women of child-bearing potential should not administer this product.

Use during pregnancy and lactation

Cattle: Can be used during pregnancy and lactation.

Horses: See section "Contraindications".

Interactions

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

Overdose

In case of overdose symptomatic treatment should be initiated.

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

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed nationally

15. OTHER INFORMATION

50 ml or 100 ml injection vial. Not all pack sizes may be marketed.