PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton for 20 ml, 50 ml, 100 ml and 250 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml,
Ethanol (96 percent) 159.8 mg/ml.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml
50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATIONS

Cattle:

Acute respiratory infection.
Diarrhoea in calves of over one week of age and young, non-lactating cattle.
Acute mastitis.

Pigs:

Non-infectious locomotor disorders.
Puerperal septicaemia and toxaemia (MMA syndrome) with antibiotic therapy.

Horses:

Acute and chronic musculo-skeletal disorders.
Pain associated with equine colic.

7. METHOD AND ROUTES 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)

Withdrawal period:
Cattle: meat and offal: 15 days; milk: 5 days.
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

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

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

Read the package leaflet before use

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OF 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

Chanelle Pharmaceuticals Manufacturing Ltd
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 08749/5022

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label for 50 ml, 100 ml and 250 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml,
Ethanol (96 percent) 159.8 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. INDICATIONS

Read package leaflet before use.

7. METHOD AND ROUTES OF ADMINISTRATION

Cattle:

SC or IV injection.

Pigs:

IM injection.

Horses:

IV injection.

8. WITHDRAWAL PERIODS

Withdrawal period:
Cattle: meat and offal: 15 days; milk: 5 days.
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

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

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

Read the package leaflet before use

13. THE WORDS 'FOR ANIMAL TREATMENT ONLY' AND CONDITIONS OF 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

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 08749/5022

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label for 20 ml bottles}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 20 mg/ml,
Ethanol (96 percent) 159.8 mg/ml.

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

20 ml

4. ROUTES OF ADMINISTRATION

Cattle:

SC or IV injection.

Pigs:

IM injection.

Horses:

IV injection.

5. WITHDRAWAL PERIODS

Withdrawal period:
Cattle: meat and offal: 15 days; milk: 5 days.
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}
Shelf life after first opening the immediate packaging: 28 days.
Once broached use by …

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET:
Rheumocam 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:
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

Manufacturers responsible for the batch release:
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland

and

Eurovet Animal Health B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands

and

Labiana Life Sciences, S.A., C/ Venus, 26, Pol. Ind. Can Parellada, Tarrasa, 08228 Barcelona

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

One ml contains:

Meloxicam 20 mg
Ethanol (96 percent) 159.8 mg
Clear, yellow solution.

4. INDICATIONS

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.

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 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 and pigs, subcutaneous, intramuscular as well as intravenous administration is well tolerated; 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 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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- 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 serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

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 musculoskeletal disorders, Rheumocam 15 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.
Maximum number of piercings is 14 for the 20 ml, 50 ml and 100 ml stoppers and 20 for the 250 ml stopper.

10. WITHDRAWAL PERIODS

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

Do not use after the expiry date (EXP) stated on the carton and vial.
Shelf life after first opening the container: 28 days.

12. SPECIAL WARNINGS

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 this package leaflet or the label to the physician.

Use during pregnancy and lactation:
Cattle and pigs**:** Can be used during pregnancy and lactation.
Horses: See 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 (symptoms, emergency procedures, antidotes):
In the case of overdose, symptomatic treatment should be initiated.

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

Waste materials should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

26/10/2020

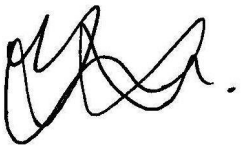
15. OTHER INFORMATION

Cardboard box containing one colourless glass injection vial of 20 ml, 50 ml, 100 ml or 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.

United Kingdom
Chanelle Vet UK Ltd
Freemans House
127 High Street
Hungerford
RG17 0DL
UK



Approved: 11 June 2021