PARTICULARS TO APPEAR ON THE OUTER PACKAGE (50 ml, 100 ml, 250 ml vial outer carton)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Contains meloxicam 20 mg/ml and ethanol (96 per cent) 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. INDICATION(S)

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 musculoskeletal disorders.
Pain associated with equine colic.

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 PERIODS

Withdrawal periods:

Cattle: Meat and offal: 15 days; Milk: 5 days (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

Read the package leaflet before use.

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}
Shelf life after first opening the immediate packaging: 28 days.
Once broached, use by_____.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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.

POM-V

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(S)

Vm 08749/4090

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (50 ml vial label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Contains meloxicam 20 mg/ml and ethanol (96 per cent) 159.8 mg/ml.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 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: SC or IV
Pigs: IM
Horses: IV

Read the package leaflet before use

8. WITHDRAWAL PERIODS

Withdrawal periods:

Cattle: Meat and offal: 15 days; milk: 5 days (120 hours)
Pigs: Meat and offal: 5 days
Horses: Meat and offal: 5 days. Not 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

Keep the container in the outer carton.

12. SPECIFIC 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.

POM-V

14. THE WORDS "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(S)

Vm 08749/4090

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (100 ml and 250 ml vial label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Contains meloxicam 20 mg/ml and ethanol (96 per cent) 159.8 mg/ml.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 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: SC or IV
Pigs: IM
Horses: IV

Read the package leaflet before use

8. WITHDRAWAL PERIODS

Cattle: Meat and offal: 15 days; milk: 5 days (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

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

Keep the container in the outer carton.

12. SPECIFIC 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.

POM-V

14. THE WORDS "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(S)

Vm 08749/4090

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PACKAGE LEAFLET FOR: FENDICAM 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 batch release:
Chanelle Pharmaceuticals Manufacturing Ltd, Loughrea, Co.Galway, Ireland
Eurovet Animal Health B.V. Handelsweg 25, 5531 AE Bladel, The Netherlands
Labiana Life Sciences, S.A., Venus, 26. Can Parellada Industrial - Tarrasa (Barcelona) - 08228 – Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

FENDICAM is a clear, yellow solution containing:

Active substance:
Meloxicam 20 mg/ml
Excipient:
Ethanol (96 per cent) 159.8 mg/ml

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.

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 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 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.
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).

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Cattle: Meat and offal: 15 days; milk: 5 days (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.
Do not use after the expiry date which is stated on the label and carton after EXP.
The expiry date refers to the last day of that month.
Shelf-life after first opening the container: 28 days.
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 determined. This discard date should be written in the space provided.
Keep the container in the outer carton.

12. SPECIAL WARNING(S)

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:
People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
Accidental self-injection may give rise to pain. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
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, the veterinary medicinal 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. See also 'Contraindications'.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticosteroids, other NSAIDs or with anti-coagulant agents.

Overdose (symptoms, emergency procedures, antidotes)
In the case of overdose, 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.

For Animal Treatment Only

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2021

15. OTHER INFORMATION

Cardboard carton containing one clear glass vial of 50ml, 100ml or 250ml of solution.
Not all pack sizes may be marketed. To be supplied only on veterinary prescription.
For any information about this veterinary medicinal product, please contact the marketing authorisation holder.
POM-V
Vm 08749/4090

Approved 10 September 2021