PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box: 10 ml, 50 ml, 100 ml or 250 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recocam 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

1 x 10 ml
1 x 50 ml
1 x 100 ml
1 x 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, IV

Pigs: IM

Horses: IV

Read the package leaflet before use.
Do not broach the stopper more than 50 times.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

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 container: 28 days
Once broached, use by ….

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read the 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

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50146/5000

17. MANUFACTURER'S BATCH NUMBER

LOT {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING UNITS

Glass vial label for 50 ml, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recocam 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

1 x 50 ml
1 x 100 ml
1 x 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, IV
Pigs: IM
Horses: IV

Read the package leaflet before use.
Do not broach more than 50 times.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

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 container: 28 days
Once broached, use by ….

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

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50146/5000

17. MANUFACTURER'S BATCH NUMBER

LOT {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial label for 10 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recocam 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

10 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC, IV

Pigs: IM

Horses: IV

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

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

Pigs: meat and offal: 5 days

Horses: meat and offal: 5 days. Not authorised to 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 container: 28 days
Once broached, use by ….

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET
Recocam 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 and manufacturer responsible for batch release:

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Recocam 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

Excipient:
Ethanol 99.9% 150 mg

Clear, 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.

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 horses producing milk for human consumption.

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

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 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.

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, oral suspensions of meloxicam 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.
Do not broach the stopper more than 50 times.

10. WITHDRAWAL PERIOD(S)

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 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.

Shelf life after first opening the container: 28 days.

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:
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.

Pregnancy and lactation:
Cattle and pigs**:** Can be used during pregnancy and lactation.
Horses: Do not use in pregnant or lactating mares.
Interactions 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.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

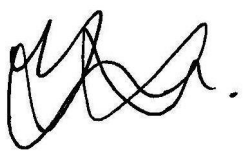
Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size of 1 Type I clear glass vial with Teflon coated bromobutyl rubber stoppers and sealed with an aluminium flip-off tear-off seal. Vials contain 10 ml, 50 ml, 100 ml or 250 ml.

Not all pack sizes may be marketed.



Approved: 24 May 2022