ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 20, 50 and 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pyrocam 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

One ml contains:

Active substance:
Meloxicam 20 mg

3. PACKAGE SIZE

20 ml
50 ml
100 ml

4. TARGET SPECIES

Cattle, pigs and horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: Single s.c. or i.v. injection.
Pigs: Single i.m. injection. If required, a second administration can be given after 24 hours.
Horses: Single i.v. injection.

7. 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 to use in horses producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Once broached, use by:

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

14. MARKETING AUTHORISATION NUMBERS

Vm 30282/3008

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials, 20 ml, 50 ml and 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pyrocam 20 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

One ml contains:

Active substance:
Meloxicam 20 mg

3. TARGET SPECIES

Cattle, pigs and horses.

4. ROUTES OF ADMINISTRATION

Cattle: s.c. or i.v. injection.
Pigs: i.m. injection.
Horses: i.v. injection.

Read the package leaflet before use.

5. 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 to use in horses producing milk for human consumption.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Once broached, use by:

7. SPECIAL STORAGE PRECAUTIONS

Store in the original package in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Huvepharma NV

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

One ml contains:

Active substance:
Meloxicam 20 mg

Excipients:
Ethanol (96 per cent) 159.8 mg

Clear yellow to yellow-green solution for injection.

3. Target species

Cattle, pigs and horses.

4. Indications for use

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 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. Special warnings

Special warnings:
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 safe use in the target species:
If adverse events 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:
This veterinary medicinal product may cause hypersensitivity (allergic reactions). People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.

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

Avoid dermal and oral exposure, including hand-to-mouth contact. Wash hands after use.

Accidental self-injection may give rise to pain. Take precautions to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Meloxicam may have adverse effects on pregnancy and/or embryofoetal development. This 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.

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

Overdose:
In case of overdose, symptomatic treatment should be initiated.

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

7. Adverse events

Cattle:

Common (<1 to 10 animals / 100 animals treated):
Injection site swelling(1)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactic-type reaction(2)

(1) following subcutaneous administration, slight, transient
(2) may be serious (including fatal), should be treated symptomatically

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactic-type reaction(3)

(3) may be serious (including fatal), should be treated symptomatically

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Injection site swelling(4)
Anaphylactic-type reaction(5)

(4) transient, resolved without intervention
(5) may be serious (including fatal), should be treated symptomatically

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

For subcutaneous or intravenous use in cattle.
For intramuscular use in pigs.
For intravenous use in horses.

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, an oral meloxicam product 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 closure may be safely punctured 15 times. In order to prevent excessive broaching of the stopper, a suitable multiple dosing device should be used.

10. 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.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions.
Store in the original package in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with

any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 30282/3008

Cardboard box with 1 glass injection vial .
Each vial is closed with a rubber stopper and sealed with an aluminium cap.

Pack sizes:
Vial with 20 ml solution for injection.
Vial with 50 ml solution for injection.
Vial with 100 ml solution for injection.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder <and contact details to report suspected adverse reactions>:
Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium
Tel: +32 3 288 18 49
E-mail: pharmacovigilance@huvepharma.com

Manufacturer responsible for batch release:
Biovet JSC
39 Petar Rakov Str
4550 Peshtera
Bulgaria

<Local representatives and contact details to report suspected adverse reactions:>

17. Other information

Gavin Hall

Approved: 12 June 2024