PARTICULARS TO APPEAR ON THE OUTER PACKAGE: CARTON 50, 100 AND 250 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. PACKAGE SIZE

50 ml

100 ml

250 ml

4. TARGET SPECIES

Cattle, pigs and horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: S.C., I.V.

Pigs: I.M.

Horses: I.V.

7. WITHDRAWAL PERIODS

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.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.
Once broached use by….

9. SPECIAL STORAGE PRECAUTIONS

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

Emdoka

14. MARKETING AUTHORISATION NUMBERS

Vm 34534/5000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE: LABEL 100 ML AND 250 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. TARGET SPECIES

Cattle, pigs and horses

4. ROUTES OF ADMINISTRATION

Cattle: SC, IV

Pigs: IM

Horses: IV

5. WITHDRAWAL PERIODS

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 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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS: LABEL 50 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.
Once broached, use by….

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:

Meloxicam 20 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Ethanol (96%)	150 mg

Clear yellow solution.

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 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:
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 for safe use in the target species:
Treatment of calves with the veterinary medicinal product20 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 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.
This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

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

Interaction with other medicinal products and other forms of interaction:
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.

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):	Anaphylactoid reaction[2]

[1]Following subcutaneous injection: slight and transient.
[2]May be serious (including fatal) and should be treated symptomatically

Pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1]

[1]May be serious (including fatal) and should be treated symptomatically.

Horses:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactoid reaction[1]Injection site swelling[2]

[1]May be serious (including fatal) and should be treated symptomatically.
[2]Transient, observed in isolated cases in clinical studies.

Reporting adverse events is important. It allows continuous safety monitoring of a 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 at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

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

For subcutaneous (**s.c.**), intramuscular (**i.m.**) or intravenous (**i.v.**) use.

Cattle
Single subcutaneous or intravenous injection at a dose 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 dose of 0.4 mg meloxicam/kg body weight (i.e. 2 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 dose of 0.6 mg meloxicam/kg body weight (i.e. 3 ml/100 kg body weight).
For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo-skeletal disorders, a suitable oral therapy containing meloxicam, administered in accordance with label recommendations, may be used for continuation of treatment.

To ensure a correct dosage, body weight should be determined as accurately as possible.

9. Advice on correct administration

Avoid introduction of contamination during use.

Do not broach the vial more than 50 times.

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 to 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 immediate packaging: 28 days

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 34534/5000

Pack size of 1 colourless Type I glass vial containing 50 ml, 100 ml or 250 ml. Each vial is closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

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:

Emdoka bvba

John Lijsenstraat 16

B-2321 Hoogstraten

Belgium

Tel: +32 (0)3 315 04 26, info@emdoka.be

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

Local representatives< and contact details to report suspected adverse events:

DUGV (UK) Ltd.

Union House, 111 New Union Street

Coventry, CV1 2NT

United Kingdom

Tel: +353 (0) 504 43169For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall
Approved: 26 March 2026