

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovem 5 mg/ml solution for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Cattle (calves and young cattle) and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: s.c. use

Pigs: i.m. use

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle: meat and offal: 15 days.

Not authorised for use in animals producing milk for human consumption.

Pigs: meat and offal: 5 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

Once broached use by...

9. SPECIAL STORAGE PRECAUTIONS

Keep the injection vial in the outer carton 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

Dopharma Research B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 28365/5002

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
GLASS VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Melovem 5 mg/ml solution for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 5 mg/ml

3. TARGET SPECIES

Cattle (calves and young cattle) and pigs

4. ROUTES OF ADMINISTRATION

Cattle: s.c.

Pigs: i.m.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle: meat and offal: 15 days.

Not authorised for use in animals producing milk for human consumption.

Pigs: meat and offal: 5 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

Once broached use by...

7. SPECIAL STORAGE PRECAUTIONS

Keep the injection vial in the outer carton in order to protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Melovem 5 mg/ml solution for injection for cattle and pigs

2. Composition

Each ml contains:

Active substance:

Meloxicam 5 mg

Excipient:

Benzyl alcohol 50 mg

Clear, greenish yellow solution.

3. Target species

Cattle (calves and young cattle) and pigs

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 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 the relief of post-operative pain associated with minor soft tissue surgery such as castration.

5. Contraindications

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.

Do not use in pigs less than 2 days old.

6. Special warnings

Special warnings:

Treatment of calves with Melovem 20 minutes before dehorning reduces post-operative pain. Melovem 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.

Treatment of piglets with Melovem before castration reduces post-operative pain. To obtain pain relief during surgery co-medication with an appropriate anaesthetic/sedative is needed.

To obtain the best possible pain relieving effect post-surgery Melovem should be administered 30 minutes before surgical intervention.

Special precautions for safe use in the target species:

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.

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 AntiInflammatory 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: Can be used during pregnancy.

Pigs: Can be used during pregnancy and lactation.

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:

In the case of overdosage, 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 and pigs:

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

¹ Transient.

² May be serious (including fatal) and should be treated symptomatically.

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 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

Cattle:

Single subcutaneous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 10.0 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:

Locomotor disorders:

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/25 kg body weight).

If required, a second administration of meloxicam can be given after 24 hours. It is recommended to administer the second injection at a different site since local tolerance has been assessed after single injection only.

Reduction of post-operative pain:

Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 0.4 ml/5 kg body weight) before surgery.

Particular care should be taken with regard to the accuracy of dosing including the use of an appropriate dosing device and careful estimation of body weight.

9. Advice on correct administration

Avoid introduction of contamination during use.

10. Withdrawal periods

Cattle: meat and offal: 15 days.

Not authorised for use in lactating animals producing milk for human consumption.

Pigs: meat and offal: 5 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the injection vial in the outer carton in order to protect from light.

This veterinary medicinal product does not require any special temperature storage conditions.

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

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

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 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 28365/5002

Cardboard box with 1 vial of 100 ml.

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:

Dopharma Research B.V.

Zalmweg 24

4941 VX Raamsdonksveer

Tel: +31-162-582000

pharmacovigilance@dopharma.com

Manufacturer responsible for batch release:

Dopharma B.V.
Zalmweg 24
4941 VX Raamsdonksveer

17. Other information

POM-V

Gavin Hall
Approved: 04 November 2025