PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Carton for 10 ml, 32 ml, 100 ml and 180 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1.5 mg/ml oral suspension for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 1.5 mg/ml

3. PACKAGE SIZE

10 ml
32 ml
100 ml
180 ml

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Shake well before use.
Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 6 months

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

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBER

Vm 61700/5055

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle, 100 ml and 180 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1.5 mg/ml oral suspension for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam: 1.5 mg/ml

100 ml
180 ml

3. TARGET SPECIES

Dogs

4. ROUTES OF ADMINISTRATION

Shake well before oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 6 months

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Bottle, 10 ml and 32 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1.5 mg/ml for dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Meloxicam: 1.5 mg/ml

10 ml
32 ml

Shake well before oral use.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 6 months

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Metacam 1.5 mg/ml oral suspension for dogs

2. Composition

Each ml contains:
Active substance: Meloxicam: 1.5 mg (equivalent to 0.05 mg per drop)
Excipient: Sodium benzoate: 1.5 mg (equivalent to 0.05 mg per drop)

Yellowish viscous oral suspension with a green tinge.

3. Target species

Dogs

4. Indications for use

Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders in dogs.

5. Contraindications

Do not use in dogs suffering from gastrointestinal disorders such as irritation or haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dogs less than 6 weeks of age.

6. Special warnings

Special precautions for safe use in the target species:
Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of renal toxicity.
This product for dogs should not be used in cats as it is not suitable for use in this species. In cats, Metacam 0.5 mg/ml oral suspension for cats should be used.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product.
In case of accidental ingestion, seek medical advice immediately and show this package leaflet or the label to the physician.

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

Pregnancy and lactation:
Do not use in pregnant or lactating animals.

Interaction with other medicinal products and other forms of interaction:
Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. This veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids.

Pre-treatment with anti-inflammatory substances may result in additional or increased adverse effects and accordingly a treatment-free period with such veterinary medicinal products should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacological properties of the products used previously.

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

Major incompatibilities:
None known.

7. Adverse events

Dogs:

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

- Appetite loss[1], lethargy[1]
- Vomiting[1], diarrhoea[1], blood in faeces[1,2], haemorrhagic diarrhoea[1], haematemesis[1], gastric ulcer[1], small intestine ulcer[1]
- Elevated liver enzymes[1]
- Renal failure[1]

[1] These adverse events occur generally within the first treatment week and are in most cases transient and disappear following termination of the treatment but in very rare cases may be serious or fatal.

[2] Occult.

If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

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: Email: adverse.events@vmd.gov.uk. Website: https://www.gov.uk/report-veterinary-medicine-problem.

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

Oral use.

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.1 mg meloxicam/kg body weight.

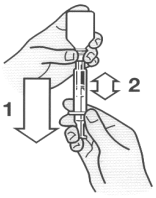
For longer term treatment, once clinical response has been observed (after ≥ 4 days), the dose of the veterinary medicinal product can be adjusted to the lowest effective individual dose reflecting that the degree of pain and inflammation associated with chronic musculo-skeletal disorders may vary over time.

To be administered orally either mixed with food or directly into the mouth.
The suspension can be given using either the drop dispenser of the bottle (for very small breeds) or the measuring syringe provided in the package.

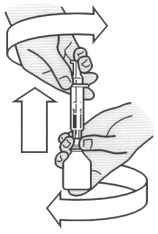
<u>Dosing procedure using the drop dispenser of the bottle:</u>
Initial dose: 4 drops/kg body weight
Maintenance dose: 2 drops/kg body weight.

<u>Dosing procedure using the measuring syringe:</u>
The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the maintenance dose. Thus for initiation of the therapy on the first day, twice the maintenance volume will be required.

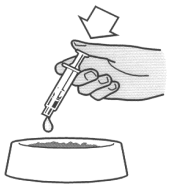
Shake bottle well. Push down and unscrew bottle top. Attach the dosing



Turn the bottle/syringe upside down. Pull the plunger out



Turn the bottle right way up and with a twisting movement



By pushing the plunger in empty the contents of the syringe onto the

syringe to the drop dispenser of the bottle by gently pushing.	until the black line on the plunger corresponds to your dog´s body weight in kilograms.	separate the dosing syringe from the bottle.	food or directly into the mouth.

Alternatively therapy may be initiated with Metacam 5 mg/ml solution for injection.

A clinical response is normally seen within 3–4 days. Treatment should be discontinued after 10 days at the latest if no clinical improvement is apparent.

9. Advice on correct administration

Particular care should be taken with regard to the accuracy of dosing. To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended. Shake well before use.
Please carefully follow the instructions of the veterinarian. Avoid introduction of contamination during use.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf life after first opening the container: 6 months.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the 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.
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 61700/5055

Cardboard box with one bottle of either 10 ml, 32 ml, 100 ml or 180 ml.
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 manufacturer responsible for batch release:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Local representatives and contact details to report suspected adverse reactions:
United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Limited
+44 1344 746957

17. Other information

POM-V	Veterinary medicinal product subject to prescription

For animal treatment only

Gavin Hall
Approved: 03 April 2025