ANNEX III

LABELLING AND PACKAGE INSERT
A. LABELLING
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Metacam 1.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES
Meloxicam 1.5 mg/ml

3. PHARMACEUTICAL FORM
Oral suspension

4. PACKAGE SIZE
10 ml

5. TARGET SPECIES
Dogs

6. INDICATION(S)
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders.

7. METHOD AND ROUTE(S) OF ADMINISTRATION
Shake well before use. To be administered mixed with food.

8. WITHDRAWAL PERIOD
Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY
Do not use in pregnant or lactating animals.
Read the package insert before use.

10. EXPIRY DATE
Exp. {month/year}
Shelf-life of opened bottle: 6 months.

11. SPECIAL STORAGE CONDITIONS
No special precautions for storage.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH VETERINARY MEDICINAL PRODUCTS, IF APPROPRIATE

Dispose of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

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

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

<table>
<thead>
<tr>
<th>Marketing authorisation holder</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim/Rhein Germany</td>
<td>Boehringer Ingelheim Pharma KG 55216 Ingelheim/Rhein Germany</td>
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</tbody>
</table>

16. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Metacam 1.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES
Meloxicam 1.5 mg/ml

3. PHARMACEUTICAL FORM
Oral suspension

4. PACKAGE SIZE
32 ml

5. TARGET SPECIES
Dogs

6. INDICATION(S)
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders.

7. METHOD AND ROUTE(S) OF ADMINISTRATION
Shake well before use. To be administered mixed with food.

8. WITHDRAWAL PERIOD
Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY
Do not use in pregnant or lactating animals.
Read the package insert before use.

10. EXPIRY DATE
Exp. {month/year}
Shelf-life of opened bottle: 6 months.
11. SPECIAL STORAGE CONDITIONS
No special precautions for storage.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH VETERINARY MEDICINAL PRODUCTS, IF APPROPRIATE
Dispose of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY”
For animal treatment only

14. THE WORDS “KEEP OUT OF THE REACH AND SIGHT OF CHILDREN”
Keep out of the reach and sight of children

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17. MANUFACTURER’S BATCH NUMBER
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18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE
Veterinary medicinal product subject to prescription.
PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR, WHERE THERE IS NO OUTER PACKAGE, ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Metacam 1.5 mg/ml oral suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES
Meloxicam 1.5 mg/ml

3. PHARMACEUTICAL FORM
Oral suspension

4. PACKAGE SIZE
100 ml

5. TARGET SPECIES
Dogs

6. INDICATION(S)
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders.

7. METHOD AND ROUTE(S) OF ADMINISTRATION
Shake well before use. To be administered mixed with food.

8. WITHDRAWAL PERIOD
Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY
Do not use in pregnant or lactating animals.
Read the package insert before use.

10. EXPIRY DATE
Exp. {month/year}
Shelf-life of opened bottle: 6 months.
11. SPECIAL STORAGE CONDITIONS

No special precautions for storage.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH VETERINARY MEDICINAL PRODUCTS, IF APPROPRIATE

Dispose of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

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

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT

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16. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

17. MANUFACTURER’S BATCH NUMBER

Batch No.:

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1.5 mg/ml oral suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 1.5 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR NUMBER OF DOSES

10 ml

4. TARGET SPECIES

Dogs

5. ROUTE(S) OF ADMINISTRATION

To be administered mixed with food.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Germany

7. BATCH NUMBER

Batch No.: 

8. EXPIRY DATE

Exp. {month/year}

9. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Metacam 1.5 mg/ml Oral Suspension

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)
Meloxicam 1.5 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR NUMBER OF DOSES
32 ml

4. TARGET SPECIES
Dogs

5. ROUTE(S) OF ADMINISTRATION
To be administered mixed with food.

6. NAME OF THE MARKETING AUTHORISATION HOLDER
Boehringer Ingelheim Vetmedica GmbH
Germany

7. BATCH NUMBER
Batch No.: 

8. EXPIRY DATE
Exp. {month/year}

9. THE WORDS “FOR ANIMAL TREATMENT ONLY”
For animal treatment only
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

   Metacam 1.5 mg/ml oral suspension

2. **QUANTITY OF THE ACTIVE SUBSTANCE(S)**

   Meloxicam 1.5 mg/ml

3. **CONTENTS BY WEIGHT, BY VOLUME OR NUMBER OF DOSES**

   100 ml

4. **TARGET SPECIES**

   Dogs

5. **ROUTE(S) OF ADMINISTRATION**

   To be administered mixed with food.

6. **NAME OF THE MARKETING AUTHORISATION HOLDER**

   Boehringer Ingelheim Vetmedica GmbH
   Germany

7. **BATCH NUMBER**

   Batch No.: 

8. **EXPIRY DATE**

   Exp. {month/year}

9. **THE WORDS "FOR ANIMAL TREATMENT ONLY"**

   For animal treatment only
B. PACKAGE INSERT
1. **NAME OF THE VETERINARY MEDICINAL PRODUCT**

Metacam 1.5 mg/ml oral suspension

2. **STATEMENT OF THE ACTIVE AND OTHER SUBSTANCE(S)**

Meloxicam 1.5 mg/ml
(equivalent to 0.05 mg per drop)

3. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE IN THE EEA, IF DIFFERENT**

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4. **TARGET SPECIES**

Dogs

5. **INDICATION(S)**

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

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class which acts by inhibition of prostaglandin synthesis, thereby exerting anti-inflammatory, analgesic, anti-exudative and antipyretic effects. It reduces leukocyte infiltration into the inflamed tissue.

6. **DOSAGE FOR EACH SPECIES**

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.

7. **METHOD AND ROUTE(S) OF ADMINISTRATION**

Shake well before use. To be administered mixed with food.

The suspension can be given using either the drop dispenser (for very small breeds) or the Metacam measuring syringe provided in the package (see below). The dispenser provides 0.05 mg meloxicam per drop (i.e. a dose of 0.1 mg meloxicam/kg body weight corresponds to 2 drops/kg body weight).
The syringe fits onto the bottle and has a kg-body weight scale which corresponds to the maintenance dose (i.e. 0.1 mg meloxicam/kg body weight). Thus for the first day, twice the maintenance volume will be required.

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

Dosing procedure using the measuring syringe:

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.

8.   ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian.

9.   CONTRAINDICATIONS

Do not use in pregnant or lactating animals.
Do not use in animals suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of individual hypersensitivity to the product.
Do not use in dogs less than 6 weeks of age.

10. UNDESIRABLE EFFECTS

Typical adverse drug reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood and apathy have occasionally been reported. These side effects 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.

11. WITHDRAWAL PERIOD

Not applicable.
12. **SPECIAL STORAGE PRECAUTIONS**

Keep out of the reach and sight of children.

Shelf-life of opened bottle: 6 months.

Do not use after the expiry date stated on the carton and the bottle.

13. **SPECIAL WARNING(S)**

If side effects occur, treatment should be discontinued and the advice of a veterinarian should be sought. Avoid use in any dehydrated, hypovolaemic or hypotensive animal, as there is a potential risk of increased renal toxicity.

Other NSAIDs, diuretics, anticoagulants, aminoglycoside antibiotics and substances with high protein binding may compete for binding and thus lead to toxic effects. Metacam 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 drugs should be observed for at least 24 hours before commencement of treatment. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.

In the case of overdosage symptomatic treatment should be initiated.

Individuals sensitive to NSAIDs should avoid contact with the product.

In case of accidental self-administration, seek medical advice immediately and show this package insert or the label to the physician.

14. **SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCT OR WASTE MATERIALS DERIVED FROM SUCH VETERINARY MEDICINAL PRODUCTS**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

15. **DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED**

08.02.02
16. **OTHER INFORMATION**

Veterinary medicinal product subject to prescription.  
10, 32 or 100 ml bottle.

For any information about this veterinary medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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