

**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**

<b>Marketing authorisation holder</b>	<b>Manufacturer</b>
Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim/Rhein Germany	Boehringer Ingelheim Pharma KG 55216 Ingelheim/Rhein Germany

**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

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

<b>Marketing authorisation holder</b>	<b>Manufacturer</b>
Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim/Rhein Germany	Boehringer Ingelheim Pharma KG 55216 Ingelheim/Rhein Germany

**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**

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**

<b>Marketing authorisation holder</b>	<b>Manufacturer</b>
Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim/Rhein Germany	Boehringer Ingelheim Pharma KG 55216 Ingelheim/Rhein Germany

**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**

## 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

Marketing authorisation holder	Manufacturer
Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim/Rhein Germany	Boehringer Ingelheim Pharma KG 55216 Ingelheim/Rhein Germany

### 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.

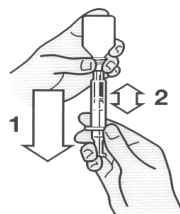
The suspension can be given using either the drop dispenser (for very small breeds) or the Metacam measuring syringe provided in the package (see below). The dispenser provides 0.05 mg meloxicam per drop (i.e. a dose of 0.1 mg meloxicam/kg body weight corresponds to 2 drops/kg body weight).

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.

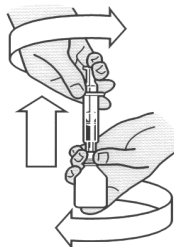
Alternatively therapy may be initiated with Metacam 5 mg/ml solution for injection.  
Dosing procedure using the measuring syringe:



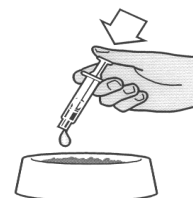
Shake bottle well.  
Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end onto the top of the bottle.



Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to your dog's bodyweight in kilograms.



Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle.



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

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 overdose 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.

### **België/Belgique/Belgien**

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### **Luxembourg/Luxemburg**

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**Italia**

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