

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box of blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1 mg chewable tablets for dogs

Metacam 2.5 mg chewable tablets for dogs

Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 1 mg/chewable tablet

Meloxicam 2.5 mg/chewable tablet

3. PHARMACEUTICAL FORM

Chewable tablets

4. PACKAGE SIZES

7 tablets
84 tablets
252 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Metacam 1 mg chewable tablets for dogs:

Oral use.

Single dose on the first day: 0.2 mg meloxicam/kg body weight. Maintenance dose: 0.1 mg meloxicam/kg body weight once daily (1 chewable tablet per 10 kg body weight).

Metacam 2.5 mg chewable tablets for dogs:

Oral use.

Single dose on the first day: 0.2 mg meloxicam/kg body weight. Maintenance dose: 0.1 mg meloxicam/kg body weight once daily (1 chewable tablet per 25 kg

body weight). Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet before use.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica
GmbH 55216 Ingelheim/Rhein
GERMANY

16. MARKETING AUTHORISATION NUMBERS

Metacam 1 mg chewable tablets
for dogs: EU/2/97/004/043 7
tablets EU/2/97/004/044 84 tablets
EU/2/97/004/045 252 tablets

Metacam 2,5 mg chewable tablets
for dogs: EU/2/97/004/046 7 tablets
EU/2/97/004/047 84 tablets
EU/2/97/004/048 252 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1 mg chewable tablets for
dogs

Metacam 2.5 mg chewable tablets
for dogs

Meloxicam

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

**PACKAGE LEAFLET:
Metacam 1 mg chewable
tablets for dogs
Metacam 2.5 mg chewable
tablets for dogs**

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

Marketing authorisation holder and manufacturer
responsible for batch release: Boehringer Ingelheim
Vetmedica GmbH
55216
Ingelheim/
Rhein
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 1 mg chewable
tablets for dogs Metacam
2.5 mg chewable tablets for
dogs Meloxicam

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

One tablet contains:
Meloxicam 1 mg
Meloxicam 2.5 mg

Round mottled beige biconvex tablet, scored on the upper side with
embedded code either "M10" or "M25" on one side. The tablet can be
divided into equal halves.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in pregnant or lactating animals.

Do not use in dogs suffering from gastrointestinal disorders such as irritation and haemorrhage, impaired hepatic, cardiac or renal function and haemorrhagic disorders.

Do not use in dogs less than 6 weeks of age or less than 4 kg body weight.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Typical adverse reactions of non-steroidal anti-inflammatory drugs (NSAIDs) such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have very rarely been reported from post-marketing safety experience.

Very rare cases of haemorrhagic diarrhoea, haematemesis, gastrointestinal ulceration and elevated liver enzymes have been reported from post-marketing safety experience.

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.

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

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF

ADMINISTRATION

Initial treatment is a single dose of 0.2 mg meloxicam/kg body weight on the first day, which can be given orally or alternatively using Metacam 5 mg/ml solution for injection for dogs and cats.

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.

Each chewable tablet contains either 1 mg or 2.5 mg meloxicam, which corresponds to the daily maintenance dose for a 10 kg body weight dog, or a 25 kg body weight dog respectively.

Each chewable tablet can be halved for accurate dosing according to the individual body weight of the dog. Metacam chewable tablets can be administered with or without food, are flavoured and are taken by most dogs voluntarily.

Dose scheme for the maintenance dose:

Body weight (kg)	Number of chewable tablets		mg/kg
	1 mg	2.5 mg	
4.0–7.0	½		0.13–0.1
7.1–10.0	1		0.14–0.1
10.1–15.0	1½		0.15–0.1
15.1–20.0	2		0.13–0.1
20.1–25.0		1	0.12–0.1
25.1–35.0		1 ½	0.15–0.1
35.1–50.0		2	0.14–0.1

The use of Metacam oral suspension for dogs may be considered for an even more precise dosing. For dogs weighing less than 4 kg the use of Metacam oral suspension for dogs is recommended.

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

9. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing. Please carefully follow the instructions of the veterinarian. Instructions for opening the child-resistant blisters: Push the tablet for release from the blister.

10. WITHDRAWAL PERIOD(S)

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. Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after EXP.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

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 carton to the physician.

Pregnancy and lactation:

See section "Contraindications".

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. 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 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 (symptoms, emergency procedures, antidotes):

In case of overdose symptomatic treatment should be initiated.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

15. OTHER INFORMATION

Package sizes:

Metacam 1 mg chewable
tablets for dogs Blisters:
7, 84 or 252 tablets.

Metacam 2.5 mg chewable
tablets for dogs Blisters: 7,
84 or 252 tablets.

Not all pack sizes may be marketed.