ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

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 Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZES

10 ml
32 ml
100 ml
180 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in pregnant or lactating animals.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months.

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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

EU/2/97/004/003 10 ml
EU/2/97/004/004 32 ml
EU/2/97/004/005 100 ml
EU/2/97/004/029 180 ml

17. MANUFACTURER'S 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 Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 1.5 mg/ml

3. PHARMACEUTICAL FORM

4. PACKAGE SIZES

100 ml
180 ml

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months.

11. SPECIAL STORAGE CONDITIONS

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

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica
GmbH GERMANY

16. MARKETING AUTHORISATION NUMBERS

EU/2/97/004/005 100 ml

EU/2/97/004/029 180 ml

17. MANUFACTURER'S 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 oral suspension
for dogs Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 1.5 mg/ml

3. CONTENT BY WEIGHT; BY VOLUME OR BY NUMBER OF DOSES

10 ml
32 ml

4. ROUTE(S) OF ADMINISTRATION

Shake well before
use.
Oral use

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Metacam 1.5 mg/ml oral suspension 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 1.5 mg/ml oral suspension
for dogs Meloxicam

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

One ml contains:
Meloxicam 1.5 mg (equivalent to 0.05 mg

per drop) Yellowish viscous oral suspension with

a green tinge.

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 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. 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

Dosage
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 Metacam 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.

Method and route of administration
Shake well before use. 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 syringe to the drop dispenser of the bottle by gently pushing.	Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to your dog´s body weight 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 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. Please carefully follow the instructions of the veterinarian.
Avoid introduction of contamination during use.

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. 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.

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 label to the physician.
This product can cause eye irritation. In case of contact with the eyes, immediately rinse thoroughly with water.

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

10 ml, 32 ml, 100 ml or 180 ml bottle. Not all pack sizes may be marketed.