ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 3 ml, 10 ml, 15 ml and 30 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 0.5 mg/ml oral suspension for cats and guinea pigs Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 0.5 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZES

3 ml
10 ml
15 ml
30 ml

5. TARGET SPECIES

Cats and guinea pigs

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.
Do not use in cats 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 cats less than 6 weeks of age.
Do not use in guinea pigs less than 4 weeks of age.

10. EXPIRY DATE

EXP {month/year}
3 ml: Once opened use within 14 days 10 ml: Once opened use within 6 months. 15 ml: Once opened use within 6 months. 30 ml: 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 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

EU/2/97/004/034 3
ml EU/2/97/004/033
10 ml
EU/2/97/004/026 15 ml
EU/2/97/004/049 30 ml

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle, 3 ml, 10 ml, 15 ml, 30 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 0.5 mg/ml oral suspension for cats and guinea pigs Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 0.5 mg/ml

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

3 ml
10 ml
15 ml
30 ml

4. ROUTE OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
3 ml: Once opened use within 14 days 10 ml:
Once opened use within 6 months. 15 ml:
Once opened use within 6 months. 30 ml:

Once opened use within 6 months.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Metacam 0.5 mg/ml oral suspension for cats and guinea pigs

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 0.5 mg/ml oral suspension for cats and guinea pigs Meloxicam

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

One ml contains:
Meloxicam 0.5 mg (equivalent to 0.017 mg

per drop). Yellowish viscous oral suspension with

a green tinge.

4. INDICATION(S)

Cats:
Alleviation of mild to moderate post-operative pain and inflammation following surgical procedures in cats, e.g. orthopaedic and soft tissue surgery.
Alleviation of pain and inflammation in acute and chronic musculo-skeletal disorders in cats.

Guinea pigs:
Alleviation of mild to moderate post-operative pain associated with soft tissue surgery such as male castration.

5. CONTRAINDICATIONS

Do not use in pregnant or lactating animals.
Do not use in cats 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 cats less than 6 weeks of age.
Do not use in guinea pigs less than 4 weeks of age.

6. ADVERSE REACTIONS

In cats, 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.
Gastrointestinal ulceration and elevated liver enzymes were reported in very rare cases from post- marketing safety experience.

These side effects 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 during)
- 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

Cats and guinea pigs

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

Cats:
Dosage
Post-operative pain and inflammation following surgical procedures:
After initial treatment with Metacam 2 mg/ml solution for injection for cats, continue treatment 24 hours later with Metacam 0.5 mg/ml oral suspension for cats at a dosage of 0.05 mg meloxicam/kg body weight. The oral follow-up dose may be administered once daily (at 24-hour intervals) for up to 4 days.

Acute musculo-skeletal disorders:
Initial treatment is a single oral 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 dose of 0.05 mg meloxicam/kg body weight for as long as acute pain and inflammation persist.

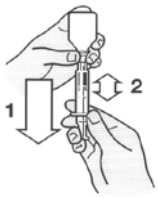
Chronic musculo-skeletal disorders:
Initial treatment is a single oral dose of 0.1 mg meloxicam/kg body weight on the first day. Treatment is to be continued once daily by oral administration (at 24-hour intervals) at a maintenance dose of 0.05 mg meloxicam/kg body weight.
A clinical response is normally seen within 7 days. Treatment should be discontinued after 14 days at the latest if no clinical improvement is apparent.

Route and method of administration
To be administered orally either mixed with food or directly into the mouth.
The suspension can be given using the drop dispenser of the bottle for cats of any body weight. Alternatively and for cats with a body weight of at least 2 kg, the measuring syringe provided in the package can be used.
Particular care should be taken with regard to the accuracy of dosing. The recommended dose should not be exceeded.

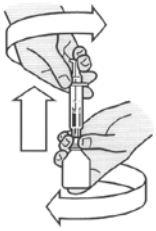
Dosing procedure using the drop dispenser of the bottle:
Dose of 0.2 mg meloxicam/kg body weight: 12 drops/kg body weight Dose of 0.1 mg meloxicam/kg body weight: 6 drops/kg body weight Dose of 0.05 mg meloxicam/kg body weight: 3 drops/kg body weight.

Dosing procedure using the measuring syringe:
The syringe fits onto the drop dispenser of the bottle and has a kg-body weight scale which corresponds to the dose of 0.05 mg meloxicam/kg bodyweight. Thus for initiation of the treatment of chronic musculo-skeletal disorders on the first day, twice the maintenance volume will be required.
For initiation of the treatment of acute musculo-skeletal disorders on the first day, 4 times 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 cat´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.

Guinea pigs:
Dosage
Post-operative pain associated with soft tissue surgery:
Initial treatment is a single oral dose of 0.2 mg meloxicam/kg body weight on day 1 (pre-surgery). Treatment is to be continued once daily by oral administration (at 24-hours intervals) at a dose of 0.1 mg meloxicam/kg body weight on day 2 to day 3 (post-surgery).

The dose can, at the discretion of the veterinarian, be titrated up to 0.5 mg/kg in individual cases. The safety of doses exceeding 0.6 mg/kg has, however, not been evaluated in guinea pigs.

Route and method of administration
The suspension should be given directly into the mouth using a standard 1 ml syringe graduated with ml scale and 0.01 ml increments.

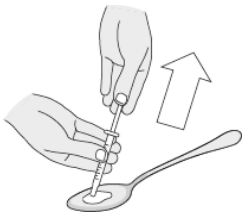
Dose of 0.2 mg meloxicam/kg body weight: 0.4 ml/kg body weight Dose of 0.1 mg meloxicam/kg body weight: 0.2 ml/kg body weight

Use a small container (e.g. a teaspoon) and drop Metacam oral suspension into the container (it is advised to dispense a few drops more than required into the small container). Use a standard 1 ml syringe to draw up Metacam according to the bodyweight of the guinea pig. Administer Metacam with the syringe directly into the mouth of the guinea pig. Wash the small container with water and dry prior to the next use.

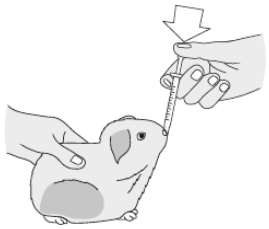
Do not use the cat syringe with the kg-body weight scale and the cat pictogram for guinea pigs.

Shake bottle well. Push down and unscrew bottle top.

Use a small container (e.g. a teaspoon) and drop Metacam oral suspension into the container (it is



Use the 1 ml standard syringe and
draw up the required volume of Metacam oral suspension which



By pushing the plunger in empty the contents of the syringe directly into the mouth of the guinea pig.

advised to dispense a few drops more than required into the small container).	corresponds to the body weight of the guinea pig.

9. ADVICE ON CORRECT ADMINISTRATION

Please carefully follow the instructions
of the veterinarian. Shake well before
use.
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:
3 ml bottle: 14 days
10 ml, 15 ml and 30 ml bottles: 6 months.

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

Post-operative use in cats and guinea pigs:
In case additional pain relief is required, multimodal pain therapy should be considered.

Chronic musculoskeletal disorders in cats:
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

Special precautions to be taken by the person administering the veterinany 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. Concurrent administration of potential nephrotoxic drugs should be avoided.

In cats, pre-treatment with anti-inflammatory substances other than Metacam 2 mg/ml solution for injection for cats at a single dose of 0.2 mg/kg 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):
Meloxicam has a narrow therapeutic safety margin in cats and clinical signs of overdose may be seen at relatively small overdose levels.
In case of overdose, adverse reactions, as listed in section "Adverse reactions", are expected to be more severe and more frequent. In case of overdose symptomatic treatment should be initiated.

In guinea pigs, an overdose of 0.6 mg/kg body weight administred during 3 days followed by a dose of
0.3 mg/kg during 6 additional days did not cause adverse events typical for meloxicam. The safety of doses exceeding 0.6 mg/kg has not been evaluated in guinea pigs.

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

3 ml, 10 ml, 15 ml or 30 ml bottle. Not all pack sizes may be marketed.