ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 5 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of Metacam 5 mg/ml solution for injection contains:

Active substance(s)

Meloxicam 5 mg

List of excipients

Ethanol, anhydrous 150 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic properties

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. To a minor extent it also inhibits collagen-induced thrombocyte aggregation.

4.2 Pharmacokinetic properties

Absorption
Following subcutaneous administration, meloxicam is completely bioavailable and maximal mean plasma concentrations of 0.73 μg/ml in dogs and 1.1 μg/ml in cats were reached approximately 2.5 hours and 1.5 hours post administration, respectively.

Distribution
There is a linear relationship between the dose administered and plasma concentration observed in the therapeutic dose range in dogs. More than 97 % of meloxicam is bound to plasma proteins. The volume of distribution is 0.3 l/kg in dogs and 0.09 l/kg in cats.

Metabolism
In dogs, meloxicam is predominantly found in plasma and is also a major biliary excretion product whereas urine contains only traces of the parent compound. Meloxicam is metabolised to an alcohol, an acid derivative and to several polar metabolites. All major metabolites have been shown to be pharmacologically inactive.

Elimination
Meloxicam is eliminated with a half-life of 24 hours in dogs and 15 hours in cats. Approximately 75 % of the administered dose is eliminated via faeces and the remainder via urine.

5. CLINICAL PARTICULARS

5.1 Target species

Dogs and cats

5.2 Indications for use

Dogs:
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats:
Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

5.3 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 animals less than 6 weeks of age nor in cats of less than 2 kg.
Do not use an oral follow-up therapy using meloxicam or other NSAIDs in cats, as no safe dosage for repeated oral administration has been established.

5.4 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.

5.5 Special precaution(s) for use

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.

5.6 Pregnancy and lactation

The safety of the veterinary medicinal product has not been established during pregnancy and lactation (See 5.3).

5.7 Interaction with other veterinary 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 animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.

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.

5.8 Posology and method of administration

Dogs:

Musculo-skeletal disorders:
Single subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight).
Metacam 1.5 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Reduction of post-operative pain:
Single intravenous or subcutaneous injection at a dosage of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg body weight) before surgery, for example at the time of induction of anaesthesia.

Cats:

Reduction of post-operative pain:
Single subcutaneous injection at a dosage of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg body weight) before surgery, for example at the time of induction of anaesthesia.

Particular care should be taken with regard to the accuracy of dosing.

Avoid introduction of contamination during use.

5.9 Overdose

In the case of overdosage symptomatic treatment should be initiated.

5.10 Special warnings for each target species

For post-operative pain relief in cats, safety has only been documented after thiopentone/halothane anaesthesia.

5.11 Withdrawal period

Not applicable.

5.12 Special precautions to be taken by the person administering the veterinary medicinal product to animals

Accidental self-injection may give rise to pain. Individuals sensitive to NSAIDs should avoid contact with the product.
In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

6. PHARMACEUTICAL PARTICULARS

6.1 Major incompatibilities

Not applicable.

6.2 Shelf life

3 years
Broached vial: 28 days

6.3 Special precautions for storage

Do not store above 25°C.

6.4 Nature and contents of container

Colourless glass injection vial of 10 ml, closed with a rubber stopper and sealed with an aluminium cap.

6.5 Special precautions for the disposal of unused veterinary medicinal products 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.

7 NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

ANNEX II

A. MANUFACTURER(S) OF THE ACTIVE SUBSTANCE(S) AND THE MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION INCLUDING RESTRICTIONS REGARDING SUPPLY AND USE

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

D. STATEMENT OF THE MRLs

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) responsible for batch release

Labiana Life Sciences S.A
Venus, 26
Can Parellada Industrial
08228 Terrassa
Spain

B. CONDITIONS OF THE MARKETING AUTHORISATION

Veterinary Medicinal product subject to medical prescription

C. PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

D. STATEMENT OF THE MRLs

Not applicable

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 5 mg/ml solution for injection for dogs and cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Meloxicam 5 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

Dogs:
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats:
Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs: Musculo-skeletal disorders: single subcutaneous injection.
Post-operative pain: single intravenous or subcutaneous injection.
Cats: Post-operative pain: single subcutaneous injection.

Avoid introduction of contamination during use.

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 broached vial: 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

Marketing authorisation holder	**Manufacturer**
Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim/Rhein Germany	Labiana Life Sciences S.A. 08228 Terrassa Spain

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 5 mg/ml solution for injection for dogs and cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 5 mg/ml

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

10 ml

4. TARGET SPECIES

Dogs and cats

5. ROUTE(S) OF ADMINISTRATION

Dogs: intravenous or subcutaneous use.
Cats: subcutaneous use.

Avoid introduction of contamination during use.

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 5 mg/ml solution for injection for dogs and cats

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

Meloxicam 5 mg/ml

Ethanol 150 mg/ml

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	Labiana Life Sciences S.A. Venus, 26 Can Parellada Industrial 08228 Terrassa Spain

4. TARGET SPECIES

Dogs and cats

5. INDICATION(S)

Dogs:
Alleviation of inflammation and pain in both acute and chronic musculo-skeletal disorders. Reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery.

Cats:
Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery.

6. DOSAGE FOR EACH SPECIES

Dogs: single administration of 0.2 mg meloxicam/kg body weight (i.e. 0.4 ml/10 kg).

Cats: single administration of 0.3 mg meloxicam/kg body weight (i.e. 0.06 ml/kg).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dogs:

Musculo-skeletal disorders: single subcutaneous injection.
Metacam 1.5 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.1 mg meloxicam/kg body weight, 24 hours after administration of the injection.

Reduction of post-operative pain: single intravenous or subcutaneous injection before surgery, for example at the time of induction of anaesthesia.

Cats:

Reduction of post-operative pain after ovariohysterectomy and minor soft tissue surgery: single subcutaneous injection before surgery, for example at the time of induction of anaesthesia.

Avoid introduction of contamination during use.

8. ADVICE ON CORRECT ADMINISTRATION

Particular care should be taken with regard to the accuracy of dosing.

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 animals less than 6 weeks of age nor in cats of less than 2 kg.
Do not use an oral follow-up therapy using meloxicam or other NSAIDs in cats, as no safe dosage for repeated oral administration has been established.

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.

If you notice any other side effects, please inform your veterinary surgeon.

11. WITHDRAWAL PERIOD

Not applicable.

12. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 25°C.
Shelf-life of broached vial: 28 days.

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. Concurrent administration of potential nephrotoxic drugs should be avoided. In animals at anaesthetic risk (e.g. aged animals) intravenous or subcutaneous fluid therapy during anaesthesia should be taken into consideration. When anaesthesia and NSAID are concomitantly administered, a risk for renal function cannot be excluded.

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.

For post-operative pain relief in cats, safety has only been documented after thiopentone/halothane anaesthesia.

Accidental self-injection may give rise to pain. Individuals sensitive to NSAIDs should avoid contact with the product. In case of accidental self-injection, 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

16. OTHER INFORMATION

Veterinary medicinal product subject to prescription.
10 ml injection vial.

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

België/Belgique/Belgien
n.v. Boehringer Ingelheim s.a.
Diergeneeskundige Afdeling/
Division Vétérinaire
Arianelaan/16 Av. Ariane
B-1200 Brussel/Bruxelles
Tel/Tél: 02-773 33 11

Danmark
Boehringer Ingelheim Danmark A/S
Strødamvej 52
DK-2100 København Ø
Tlf: 39 15 88 88

Deutschland
Boehringer Ingelheim
Vetmedica GmbH
Binger Straße 173
D-55216 Ingelheim/Rhein
Tel: 01803 660 660

Ελλάδα
Π.Ν. ΓΕΡΟΛΥΜΑΤΟΣ Α.Ε.Β.Ε.
Ασκληπιού 13,
GR-145 68 Κρυονέρι Αττικής
Τηλ.: 010 8194 203

España
Boehringer Ingelheim España, S.A.
División Veterinaria
Prat de la Riba, s/n
Sector Turó de Can Matas
E-08190 Sant Cugat del Vallès (Barcelona)
Tel: 93 404 51 00

France
Boehringer Ingelheim France
Division Santé Animale
12, rue André Huet - B.P. 292
F-51060 Reims Cedex
Tél: 03 26 50 47 50

Ireland
Boehringer Ingelheim Limited
Ellesfield Avenue
Bracknell, Berkshire
UK-RG12 8YS
Tel: +44-1344 424 600

Luxembourg/Luxemburg
n.v. Boehringer Ingelheim s.a.
Diergeneeskundige Afdeling/
Division Vétérinaire
Arianelaan/16 Av. Ariane
B-1200 Brussel/Bruxelles
Tel/Tél: +32-2-773 33 11

Nederland
Boehringer Ingelheim bv
Berenkoog 28
NL-1822 BJ Alkmaar
Tel: 072 566 24 11

Norge
Boehringer Ingelheim Vetmedica A/S
Drengsrudbekken 25
Postboks 405
N-1373 Asker
Tel: 66 76 13 20

Österreich
Boehringer Ingelheim Austria GmbH
Dr. Boehringer Gasse 5-11
A-1121 Wien
Tel: 01-80 105 0

Portugal
Vetlima
Sociedade Distribuidora de Produtos
Agro-Pecuários Lda.
Av. 5 de Outubro, 35 - 3° Esq.
P-1050-047 Lisboa
Tel: 21 354 22 11

Suomi/Finland
Vetcare Oy
PL/PB 99
FIN-24101 Salo
Puh/Tln: 02 72 72 72

Sverige
Boehringer Ingelheim Vetmedica
Box 467
S-201 24 Malmö
Tln: 040 23 34 00

Ísland
Pharmaco hf.
Hörgatún 2
IS-210 Garðabær
Sími 535 7000

Italia
Boehringer Ingelheim Italia s.p.a.
Divisione Vetmedica
Località Prulli, 103/C
I-50066 Reggello (Firenze)
Tel: 055-8650-1

United Kingdom
Boehringer Ingelheim Limited
Ellesfield Avenue
Bracknell, Berkshire
UK-RG12 8YS
Tel: 0134 4424 600