ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 20 ml, 50 ml, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 20 mg/ml solution for injection for cattle, pigs and horses
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZES

1 x 20 ml
1 x 50 ml
1 x 100 ml
1 x 250 ml
12 x 20 ml
12 x 50 ml
12 x 100 ml
6 x 250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Single SC or IV injection.
Pigs: Single IM injection. If required, a second administration can be given after 24 hours.
Horses: Single IV injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle: meat and offal: 15 days; milk: 5 days
Pigs: meat and offal: 5 days
Horses: meat and offal: 5 days.
Not authorised to use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days.

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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

Vm 04491/5021

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vials, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 20 mg/ml solution for injection for cattle, pigs and horses
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 20 mg/ml

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE(S)

100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: SC or IV injection
Pigs: IM injection.
Horses: IV injection.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle: meat and offal: 15 days; milk: 5 days
Pigs: meat and offal: 5 days
Horses: meat and offal: 5 days.
Not authorised to use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days.

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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

Vm 04491/5021

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial, 20 ml and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 20 mg/ml solution for injection for cattle, pigs and horses
Meloxicam

2. QUANITITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 20 mg/ml

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

20 ml
50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC or IV
Pigs: IM
Horses: IV

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle: meat and offal: 15 days; milk: 5 days
Pigs: meat and offal: 5 days
Horses: meat and offal: 5 days.
Not authorised to use in horses producing milk for human consumption.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 28 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Metacam 20 mg/ml solution for injection for cattle, pigs and horses

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

Marketing authorisation holder
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturers responsible for batch release
Labiana Life Sciences S.A.
Venus, 26
Can Parellada Industrial
08228 Terrassa, Barcelona
SPAIN

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 20 mg/ml solution for injection for cattle, pigs and horses
Meloxicam

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

One ml contains:

Meloxicam	20 mg
Ethanol	150 mg

Clear yellow solution.

4. INDICATION(S)

Cattle:
For use in acute respiratory infection with appropriate antibiotic therapy to reduce clinical signs in cattle.
For use in diarrhoea in combination with oral re-hydration therapy to reduce clinical signs in calves of over one week of age and young, non-lactating cattle.
For adjunctive therapy in the treatment of acute mastitis, in combination with antibiotic therapy.
For the relief of post-operative pain following dehorning in calves.

Pigs:
For use in non-infectious locomotor disorders to reduce the symptoms of lameness and inflammation.
For adjunctive therapy in the treatment of puerperal septicaemia and toxaemia (mastitis-metritis-agalactia syndrome) with appropriate antibiotic therapy.

Horses:
For use in the alleviation of inflammation and relief of pain in both acute and chronic musculo-skeletal

disorders.
For the relief of pain associated with equine colic.

5. CONTRAINDICATIONS

Do not use in horses less than 6 weeks of age.
Do not use in pregnant or lactating mares.
Do not use in animals suffering from impaired hepatic, cardiac or renal function and haemorrhagic disorders, or where there is evidence of ulcerogenic gastrointestinal lesions.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
For the treatment of diarrhoea in cattle, do not use in animals of less than one week of age.

6. ADVERSE REACTIONS

In cattle, only a slight transient swelling at the injection site following subcutaneous administration was observed in less than 10 % of the cattle treated in clinical studies.

In horses, a transient swelling at the injection site was observed in isolated cases in clinical studies, but resolved without intervention.

Anaphylactoid reactions, which may be serious (including fatal), have been observed very rarely from post-marketing safety experience and should be treated symptomatically.

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

Cattle, pigs and horses

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

Cattle:
Single subcutaneous or intravenous injection at a dosage of 0.5 mg meloxicam/kg body weight (i.e. 2.5 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Pigs:
Single intramuscular injection at a dosage of 0.4 mg meloxicam/kg body weight (i.e. 2.0 ml/100 kg body weight) in combination with antibiotic therapy, as appropriate. If required, a second administration of meloxicam can be given after 24 hours.

Horses:
Single intravenous injection at a dosage of 0.6 mg meloxicam/kg body weight (i.e. 3.0 ml/100 kg body weight).

For use in the alleviation of inflammation and the relief of pain in both acute and chronic musculo-skeletal disorders, Metacam 15 mg/ml oral suspension may be used for continuation of treatment at a dosage of 0.6 mg meloxicam/kg body weight, 24 hours after administration of the injection.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid introduction of contamination during use.

10. WITHDRAWAL PERIOD(S)

Cattle: meat and offal: 15 days; milk: 5 days
Pigs: meat and offal: 5 days
Horses: meat and offal: 5 days.
Not authorised to use in horses producing milk for human consumption.

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

12. SPECIAL WARNING(S)

Treatment of calves with Metacam 20 minutes before dehorning reduces post-operative pain. Metacam alone will not provide adequate pain relief during the dehorning procedure. To obtain adequate pain relief during surgery co-medication with an appropriate analgesic is needed.

Special precautions for use in animals:
If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.
Avoid use in very severely dehydrated, hypovolaemic or hypotensive animals which require parenteral rehydration, as there may be a potential risk of renal toxicity.
In case of inadequate relief of pain when used in the treatment of equine colic, careful re-evaluation of the diagnosis should be made as this could indicate the need for surgical intervention.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental self-injection may give rise to pain. People with known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the veterinary medicinal product.
In case of accidental self-injection, 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:
Cattle and pigs: Can be used during pregnancy and lactation.
Horses: Do not use in pregnant or lactating mares.

Interaction with other medicinal products and other forms of interaction:
Do not administer concurrently with glucocorticosteroids, other non-steroidal anti-inflammatory drugs or with anticoagulant agents.

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

Cardboard box with either 1 or 12 colourless glass injection vial(s) of 20 ml, 50 ml or 100 ml.
Cardboard box with either 1 or 6 colourless glass injection vial(s) of 250 ml.
Not all pack sizes may be marketed.