

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 50 ml and 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 40 mg/ml solution for injection for cattle and horses
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCES

Meloxicam 40 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZES

50 ml
100 ml
12 x 50 ml
12 x 100 ml

5. TARGET SPECIES

Cattle and horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: subcutaneous use, intravenous use.

Horses: Intravenous use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Cattle: meat and offal: 15 days; milk: 5 days.

Horses: meat and offal: 5 days.

Not authorised for 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 NUMBER(S)

Vm 04491/5023

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial, 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 40 mg/ml solution for injection for cattle and horses
Meloxicam

2. STATEMENT OF ACTIVE SUBSTANCE

Meloxicam 40 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE(S)

100 ml

5. TARGET SPECIES

Cattle and horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: SC, IV
Horses: IV

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Cattle: meat and offal: 15 days; milk: 5 days.

Horses: meat and offal: 5 days.

Not authorised for 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 04491/5023

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial, 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 40 mg/ml injection for cattle and horses
Meloxicam

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Meloxicam 40 mg/ml

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Cattle: SC, IV
Horses: IV

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Cattle: meat and offal: 15 days; milk: 5 days.

Horses: meat and offal: 5 days.

Not authorised for 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 40 mg/ml solution for injection for cattle 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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Metacam 40 mg/ml solution for injection for cattle and horses
Meloxicam

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One ml contains:

Active substance:

Meloxicam 40 mg

Excipient:

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.

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 (see section “Pregnancy and lactation”).
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 and horses.

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

Cattle:

Single subcutaneous or intravenous injection at a dose of 0.5 mg meloxicam/kg body weight (i.e. 1.25 ml/100 kg body weight) in combination with antibiotic therapy or with oral re-hydration therapy, as appropriate.

Horses:

Single intravenous injection at a dose of 0.6 mg meloxicam/kg body weight (i.e. 1.5 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 dose 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.

Horses: meat and offal: 5 days.

Not authorised for 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 label after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species:

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 the package leaflet or the label to the physician.

In view of the risk of accidental self-injection and the known adverse class-effects of NSAIDs and other prostaglandin inhibitors on pregnancy and/or embryofetal development, the veterinary medicinal product should not be administered by pregnant women or women attempting to conceive.

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

Pregnancy and lactation:

Cattle: Can be used during pregnancy and lactation.

Horses: Do not use in pregnant or lactating mares (see section "Contraindications").

Interaction with other medicinal products and other forms of interaction:

Do not administer concurrently with glucocorticosteroids, other NSAIDs or with anticoagulant agents.

Overdose (symptoms, emergency procedures, antidotes):

In case of overdose, symptomatic treatment should be initiated.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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

Pack sizes of 1 or 12 colourless glass injection vial(s) of 50 ml or 100 ml.
Not all pack sizes may be marketed.