ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with vial(s) of 50 ml, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Labiprofen 150 mg/ml solution for injection for cattle, pigs and horses
Ketoprofen

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Ketoprofen 150 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 x 50 ml
1 x 100 ml
1 x 250 ml
12 x 50 ml
10 x 100 ml
10 x 250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

7. METHOD AND ROUTES OF ADMINISTRATION

Intramuscular or intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:
Meat and offal: 2 days
Milk: zero hours

Horses:
Meat and offal: 1 day
Milk: Not authorised for use in mares producing milk for human consumption

Pig:
Meat and offal: 3 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.
Use by: ….

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

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

Labiana Life Sciences SA
Calle Venus 26
Can Parellada
E-08228 Terrassa
Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32112/4003

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

50 ml, 100 ml and 250 ml Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Labiprofen 150 mg/ml solution for injection for cattle, pigs and horses
Ketoprofen

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Ketoprofen 150 mg

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

7. METHOD AND ROUTES OF ADMINISTRATION

Intramuscular or intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:
Meat and offal: 2 days
Milk: zero hours

Horses:
Meat and offal: 1 day
Milk: Not authorised for use in mares producing milk for human consumption

Pig:
Meat and offal: 3 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.
Use by: ….

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light..

12. SPECIAL 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

Labiana Life Sciences SA
Calle Venus 26
Can Parellada
E-08228 Terrassa
Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 32112/4003

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Labiprofen 150 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 and manufacturer responsible for batch release:
Labiana Life Sciences SA – Calle Venus 26 – Can Parellada – E-08228 Terrassa - Barcelona - Spain.

Local representative of the marketing authorisation holder:
Cross Vetpharm Group UK Ltd. (T/A Bimeda),
Unit 2, Bryn Cefni Industrial Park, Llangefni, Anglesey, LL77 7XA,
United Kingdom
Tel: 01248 725400 e-mail: uksales@bimeda.com

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Labiprofen 150 mg/ml solution for injection for cattle, pigs and horses
Ketoprofen

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:
Active substance:
Ketoprofen 150 mg
Excipients:
Benzyl alcohol (E1519) 10 mg

A clear colourless to yellowish solution

4. INDICATIONS

Cattle:
- Reduction of inflammation and pain associated with post-partum, musculoskeletal disorders and lameness.
- Reduction of fever associated with bovine respiratory disease in combination with antimicrobial therapy where appropriate.
- Reduction of inflammation, fever and pain in acute clinical mastitis in combination with antimicrobial therapy where appropriate.

Pigs:
- Reduction of pyrexia in cases of respiratory disease and Postpartum Dysglactia SyndromePDS- (Metritis Mastitis Agalactia syndrome) in sows, in combination with antimicrobial therapy, where appropriate.

Horses:
- Reduction of inflammation and pain associated with osteoarticular and musculoskeletal disorders (lameness, laminitis, osteoarthritis, synovitis, tendinitis, etc.).

- Reduction of postoperative pain and inflammation.
- Reduction of visceral pain associated with colic.

5. CONTRAINDICATIONS

Do not use in animals where there is the possibility of gastro-intestinal ulceration or bleeding, in order not to aggravate their situation.
Do not use in animals suffering from cardiac, hepatic, or renal disease.
Do not use in cases of known hypersensitivity to ketoprofen or acetyl-salcylic acid or to any of the excipients.
Do not use in animals with evidence of blood dyscrasia or coagulopathy. Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.

6. ADVERSE REACTIONS

Intramuscular injection of ketoprofen can cause mild, transient, necrotic subclinical muscular lesions that gradually resolve in the days after completion of treatment. Administration in the neck region minimizes the extension and severity of these lesions.

In horses, transient local reactions, which disappeared after 5 days, were observed after one administration of the product at the recommended volume by extravascular route.

Due to the mechanism of action of ketoprofen, after repeated administrations, erosive and ulcerative lesions of the gastrointestinal tract may occur.

In common with all NSAIDs due to their action of inhibition of prostaglandins' synthesis, there can be the possibility in certain individuals of gastric or renal intolerance.

If side effects occur treatment must be stopped and the advice of a veterinarian should be sought.

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.

Alternatively, you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, pigs and horses

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

Intramuscular or intravenous use.

- Cattle:
3 mg ketoprofen/kg body weight, i.e. 1ml of product per 50 kg body weight/ day, administered via the intravenous or intramuscular route, preferably in the neck region.
The duration of treatment is 1-3 days, and should be established according to the severity and duration of symptoms.

- Pigs:
3 mg of ketoprofen/kg body weight i.e. 1 ml of the product per 50 kg body weight/ day, administered via the intramuscular route on a single occasion. Depending on the response observed and based on the benefit-risk analysis by the responsible veterinarian treatment may be repeated at intervals of 24 hours for a maximum of three treatments. Each injection should be given at a different site.

- Horses:
2.2 mg of ketoprofen/kg body weight, i.e. 0.75 ml of the product. per 50 kg body weight/ day, administered via the intravenous route.
The duration of treatment is 1-5 days, and should be established according to the severity and duration of symptoms. In the case of colic one injection is normally sufficient. A second administration of ketoprofen requires a clinical re-examination.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIODS

Cattle:
Meat and offal: 2 days
Milk: zero hours

Horses:
Meat and offal: 1 day
Milk: Not authorised for use in mares producing milk for human consumption

Pig:
Meat and offal: 3 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNINGS

Special precautions for use in animals:
Do not exceed the recommended dose. Do not exceed the recommended treatment period.
The use of ketoprofen is not recommended in foals less than one month of age.

When administering to animals of less than 6 weeks of age, ponies or in aged animals it is necessary to adjust the dose accurately as well as to perform a close clinical follow-up.
Avoid intra-arterial injection.
Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

Since gastric ulceration is a common finding in PMWS (Post-weaning Multisystemic Wasting Syndrome), the use of ketoprofen in pigs affected by this pathology is not recommended, in order not to aggravate their situation. In horses, avoid extravascular administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Hypersensitivity reactions (skin rash, urticaria) could occur. People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product.
Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid contact with the skin, eyes and mucous membranes. In case of accidental skin, eye or mucous membrane contact, wash the affected area thoroughly with clean running water immediately. Seek medical advice if irritation persists.
Wash hands after use.

Pregnancy and lactation:
Studies in laboratory animals (rats, mice, rabbits) and cattle have not produced any evidence of adverse effects. Can be used in pregnant cows.
The safety of the veterinary medicinal product has not been established during pregnancy in sows and mares. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.
Can be used in lactating cows and sows.
The use is not recommended in lactating mares.

Interaction with other medicinal products and other forms of interaction:
- Concurrent administration of diuretics or potentially nephrotoxic drugs should be avoided since there is an increase of renal disturbances, including renal failure. This is secondary to the diminished blood flow caused by the inhibition of prostaglandins synthesis.
- Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, anticoagulants or diuretics concurrently or within 24 hours of administration of the product since the risk of gastrointestinal ulceration and other adverse reactions may be exacerbated.
- The treatment free period should however take into account the pharmacological properties of the products used previously.
- Ketoprofen is highly bound to plasma proteins and may compete with other highly bound drugs which can lead to toxic effects.

Overdose (symptoms, emergency procedures, antidotes):
Overdose with non-steroidal anti-inflammatory drugs can lead to gastro-intestinal ulceration, loss of proteins, hepatic and renal impairment.

In tolerance studies performed in pigs, up to 25% of the animals treated at three times the maximum recommended dose (9 mg/kg bw) for three days or at the recommended dose (3 mg/kg bw) for triple the maximum recommended time (9 days) showed erosive and/or

ulcerative lesions in both the aglandular (pars oesophagica) and glandular parts of the stomach. Early signs of toxicity include loss of appetite and pasty faeces or diarrhoea.

The intramuscular administration of the product to cattle, at up to 3 times the recommended dose or for 3 times the recommended duration of the treatment (9 days) did not result in clinical signs of intolerance. However, inflammation as well as necrotic subclinical lesions

were detected at the injection site of the treated animals as well as an increase in CPK levels. The histopathological examination showed erosive or ulcerative abomasal lesions related to both dosage regimes.

Horses have been found to tolerate intravenous dosages of ketoprofen up to 5 times the recommended dose for three times the recommended duration (15 days) with no evidence of toxic effects.

If clinical signs of overdose are observed, there is no specific antidote, therefore symptomatic treatment should be initiated.

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 in wastewater.
Ask your veterinary surgeon or pharmacist 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

MM/YYYY

15. OTHER INFORMATION

Package sizes:
Box containing 1 vial of 50 ml
Box containing 1 vial of 100 ml
Box containing 1 vial of 250 ml
Box containing 12 vials of 50 ml
Box containing 10 vials of 100 ml
Box containing 10 vials of 250 ml

Not all pack sizes may be marketed.

For animal treatment only.

For any information about this veterinary medicinal product, please contact the marketing authorisation holder.

Approved 02 March 2021