B. PACKAGE LEAFLET

PACKAGE LEAFLET:

KETOPROCEN 100 mg/ml SOLUTION FOR INJECTION

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:

CENAVISA S.L.
Camí Pedra Estela s/n
43205 Reus (SPAIN)
Tel. 34 977 757 273

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

KETOPROCEN 100 mg/ml SOLUTION FOR INJECTION for horses, cattle and pigs

Ketoprofen

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

Each ml contains:

Active substance:

Ketoprofen 100 mg

Excipients:

Benzyl alcohol (E1519) 10 mg

Other excipients q.s.

Clear yellowish solution free from visible particles.

4. INDICATION(S)

Horses:
- Alleviation of inflammation and pain associated with musculoskeletal disorders.
- Symptomatic treatment of visceral pain associated with colic. Postoperative pain and inflammation.

Cattle:
- Anti-inflammatory and analgesic treatment of diseases of musculoskeletal system.
- Reducing the pyrexia and distress associated with bacterial respiratory disease when used in connection with anti-microbial therapy as appropriate.
- Reducing mammary oedema.
- Anti-inflammatory, analgesic and anti-pyretic treatment in acute clinical mastitis signs of mastitis in conjunction with antimicrobial therapy.

Pigs:
- Reducing the pyrexia in respiratory diseases.
- Treatment of Postpartum Dysgalactia Syndrome, Mastitis Metritis Agalactia Syndrome.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in animals suffering from cardiac, hepatic or renal disease.

Do not use in animals where there is the possibility of gastro-intestinal ulceration or bleeding.

Do not use in animals where there is evidence of a blood dyscrasia or blood clotting disorders.

Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.

Do not administer in association with corticoids, diuretics or anticoagulants.

6. ADVERSE REACTIONS

Irritation or gastro-intestinal ulceration may appear very rarely.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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.

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

7. TARGET SPECIES

Horses, cattle and pigs.

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

Intramuscular or intravenous use.

Horses: Intravenous injection.

- For use in musculoskeletal conditions, the dosage is 2.2 mg of ketoprofen per kg b.w., equivalent to 1 ml of product for each 45 kg of bodyweight, once daily for up 3 to 5 days.

- For use in colic, the dosage is 2.2 mg of ketoprofen per kg, i.e. 1 ml of product for each 45 kg of bodyweight, in a single injection.

Generally a single injection is sufficient: any additional injection should be preceded by a clinical re-assessment of the animal.

Cattle:

Intramuscular or intravenous injection.

Recommended dose: 3 mg ketoprofen/kg b.w., equivalent to 1ml of product for each 33 kg of bodyweight, once daily for up to 1 to 3 days.

Pigs:

Intramuscular injection.

Recommended dose: 3 mg/kg b.w., equivalent to 1 ml of product for each 33 kg of bodyweight, in a single dose.

9. ADVICE ON CORRECT ADMINISTRATION

Do not mix with another substance in the same syringe.

For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper. The cap may be safely punctured up to 30 times.

10. WITHDRAWAL PERIOD(S)

Horses: Meat and offal: 4 days.

Milk: zero hours.

Cattle: Meat and offal: 4 days

Milk: zero hours

Pigs: Meat and offal: 4 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 label after {EXP}. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:

None.

Special precautions for use in animals:

The use of ketoprofen is not recommended in foals less than 15 days of age. Use in any animals less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided animals may require a reduced dosage and careful management.

Avoid intra-arterial injection.

Do not exceed the stated dose or duration of treatment.

Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity. Sufficient water intake should be provided during treatment.

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

People with known hypersensitivity to the active substance and/or benzyl alcohol 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.

Avoid splashes on the skin and eyes. Irrigate thoroughly with water should this occur. If irritation persists seek medical advice.

Wash hands after use.

Pregnancy and lactation:

Laboratory studies in rats, mice and rabbits; and in cattle have not produced any evidence of a teratogenic or embryotoxic effects. Can be used during pregnancy and lactation in cattle.

The safety of the veterinary medicinal product has not been established during the fertility, pregnancy or foetal health in horses. Do not use in pregnant mares.

The safety of the veterinary medicinal product has not been established during pregnancy in sows. Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Do not administer with other non-steroidal anti-inflammatory drugs, glucocorticoids or with diuretics or anticoagulants.

Ketoprofen may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

Concurrent administration with nephrotoxic drugs should be avoided.

As ketoprofen may inhibit the platelet aggregation and provoke gastrointestinal ulcerations, it should not be use with other medicinal products with the same adverse reactions profile.

Overdose (symptoms, emergency procedures, antidotes):

No clinical signs were observed when ketoprofen was administered to horses at 5 times the recommended dose for 15 days, or to cattle at 5 times the recommended dose for 5 days, or to pigs at 3 times the recommended dose for 3 days.

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 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

15. OTHER INFORMATION

Package sizes:

- Cardboard box with 1 vial of 50 ml
- Cardboard box with 1 vial of 100 ml
- Cardboard box with 1 vial of 250 ml
- Cardboard box with 10 vials of 50 ml
- Cardboard box with 10 vials of 100 ml
- Cardboard box with 10 vials of 250 ml

Not all pack sizes may be marketed.

For animal treatment only. To be supplied only on veterinary prescription.

Administration conditions: Administration by a veterinarian surgeon (in case of intravenous route) or under their direct responsibility.