B. LEAFLET

LEAFLET:
EPRINOVET 5 mg/ml pour-on solution for beef and dairy cattle

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:

LABORATORIOS CALIER, S.A.
C/ Barcelonès, 26 (Pla de Ramassà)
08520 Les Franqueses del Vallès, (Barcelona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EPRINOVET 5 mg/ml pour-on solution for beef and dairy cattle
Eprinomectin

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

Each ml contains:

Active substance:
Eprinomectin ..... 5 mg

Excipients:
Butylhydroxytoluene (E-321) ..... 0.1 mg
All-rac-α-tocopherol (E 307) ..... 0.01- 0.04 mg

Clear, slightly yellow solution.

4. INDICATION(S)

Treatment of infections by the following parasites sensitive to eprinomectin:

Gastrointestinal Roundworms (adults and L4 larval stages)
Ostertagia ostertagi (including inhibited L4 larval stages)
Ostertagia (Skrjabinagia) lyrata (adult)
Ostertagia spp.
Haemonchus placei
Trichostrongylus axei
*Trichostrongylus colubriformis**
Trichostrongylus spp.
*Cooperia spp. (*including inhibited L4 larval stages*)*
Cooperia oncophora
Cooperia punctata
Cooperia pectinata
Cooperia surnabada
Bunostomum phlebotomum
Nematodirus helvetianus

Oesophagostomum radiatum
Oesophagostomum spp. (adult)
Trichuris spp. (adult)

* Rare in cattle

Lungworms
Dictyocaulus viviparus (adult and stage L4 larval stages)

Warbles (parasitic stages)
Hypoderma bovis
Hypoderma lineatum

Lice
Linognathus vituli
Haematopinus eurysternus
Solenopotes capillatus

Biting lice
Bovicola bovis

Mange mites
Chorioptes bovis
Sarcoptes scabiei var. bovis

Horn flies
Haematobia irritans
Prolonged efficacy up to 7 days after application.
The product prevents infections with *Ostertagia spp.*, *Oesophagostomum radiatum* and *Dictyocaulus viviparus* for up to 28 days after treatment, infections with *Cooperia spp.* and *Trichostrongylus spp*. for up to 21 days after treatment, and infections with *Haemonchus placei* and *Nematodirus helvetianus* for up to 14 days after treatment. The duration of persistent efficacy can be variable for *Cooperia spp* and *H. placei* 14 days after treatment in particular in young and lean animals at the time of treatment.

5. CONTRAINDICATIONS

Do not use in other animal species.

Do not use in animals with known hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

In very rare cases, transient licking reactions, skin tremor at the administration site, minor local reactions such as the occurrence of dandruff and skin scales at the administration site have been observed.

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

Cattle (beef and dairy cattle).

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

Pour-on use. For single application only.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible and accuracy of the dosing device should be checked. All the animals belonging to the same group should be treated at the same time.

To be administered topically in one single dose at the dose rate of 500 µg eprinomectin per kg bodyweight equivalent to 1 ml per 10 kg bodyweight. Apply the pour-on solution along the backline in a narrow strip extending from the withers to the tailhead.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- and overdosing.

For the treatment of a group of animals of the same or of a similar age, the dosing should be done according to the heaviest animal of this group

9. ADVICE ON CORRECT ADMINISTRATION

- 1 L presentation:

The use of this format (1 L) is limited to animals of at least 100Kg

The bottle is equipped with an integrating dosing system, and has two openings. One opening is connected to the body of the container and the other one to the dispensing chamber (dosing system).

Unscrew the tamper-evident cap and remove the seal of the dispensing chamber (integrated dosing system allowing doses from 10 to 50 ml every 10ml).

Squeeze the bottle to fill the dispensing chamber with the required volume of product.In case of doses not being multiples of 10ml, the upper dose should be used in order to avoid development of resistance to anthelmintic drugs.

- 2.5 and 5 L presentation:

To be used with an appropriate dosing system such a dosing gun and coupling vented cap.

Unscrew the polypropylene (PP) simple cap. Remove the protective seal from the bottle. Screw a coupling vented cap on the bottle and make sure it is tightened. Connect the other side of the vented cap to the tube of a dosing gun.

Follow the gun manufacturer's instructions for adjusting the dose and proper use and maintenance of the dosing gun and vented cap.

After use, coupling vented caps should be removed and replaced by PP simple cap.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 15 days.
Milk: zero hours.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

1L bottle: Keep the bottle in the outer carton in order to protect from light.

2.5 and 5L bottles: This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

Shelf life after first opening the container: 18 months.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Strategies that should be avoided because they might lead to an increased risk of development of resistance to anthelmintic drugs include:
- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dosing device (if any).

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

To date no resistance to eprinomectin (a macrocyclic lactone) has been reported in cattle and sheep while resistance to eprinomectin has been reported in goats within the EU. Resistance to other macrocyclic lactones has been reported in nematode populations in ruminants within the EU, which may be associated with side-resistance to eprinomectin. Therefore, use of this product should be based on local

(regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

Selection of resistant genes leading to the development of resistance can ultimately result in ineffective anthelmintic therapy.

If there is a risk for re-infection, the advice of a veterinarian should be sought regarding the need for and frequency of repeat administration.

For the best results the product should be part of a programme to control both internal and external parasites of cattle based on the epidemiology of these parasites.

Rainfall before or after the application of the product has been shown to have no impact on the efficacy of the product. The impact of extreme weather conditions on the long-term efficacy (persistency) of the veterinary medicinal product is unknown.

In order to limit cross-transfer of eprinomectin, treated animals may be separated from untreated animals. Non-compliance with this recommendation may lead to residue violations in untreated animals

Special precautions for use in animals:

For external use only.

The application of the veterinary medicinal product to mud or manure covered skin areas may affect the efficacy.
The veterinary medicinal product should be applied only to healthy skin areas.
The death of warble fly larvae in the oesophagus or spinal cord canal may lead to secondary reactions.
In order to avoid secondary reactions due to the death of Hypoderma larvae in the oesophagus or the spine, it is recommended to administer the product at the end of the period of fly activity and before the larvae reach their resting site

Avermectins may be poorly tolerated by other species. Cases of intolerance have been reported in dogs, especially collies, bobtails, and related breeds and / or cross breeds. This also applies to turtles.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke, eat or drink while handling the product.
Wash hands after use.
This product may be irritating to skin and eyes. Avoid contact with eyes and skin
People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the product.
Operators should wear rubber gloves, boots and waterproof coat when applying the product.
Should clothing become contaminated, remove as soon as possible and launder before re-use.
If accidental skin contact occurs, wash the affected area immediately with soap and water.

Should accidental eye exposure occur, flush eyes immediately with plenty of clean water. Should irritation persist, seek medical advice.
Do not ingest.
In case of accidental ingestion, rinse out mouth thoroughly with water, seek medical advice immediately and show the package insert or the label to the physician.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Other precautions:

Eprinomectin is very toxic to aquatic organisms, is persistent in soils and may accumulate in sediments.
Faeces containing eprinomectin excreted onto pasture by treated animals may temporarily reduce the abundance of dung feeding organisms. Following treatment of cattle with the product, levels of eprinomectin that are potentially toxic to dung fauna species may be excreted over a period of more than 4 weeks and may decrease dung fly abundance during that period. In case of repeated treatments with eprinomectin (as with products of the same anthelmintic class) it is advisable not to treat animals every time on the same pasture to allow dung fauna populations to recover.

Eprinomectin is inherently toxic to aquatic organisms. The product should be used only according to the label instructions. Based on the excretion profile of eprinomectin when administered as the pour-on formulation, treated animals should not have access to watercourses during the first 7 days after treatment.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose (symptoms, emergency procedures, antidotes):
Animals treated with up to 10 times the therapeutic dose showed transient mydriasis.
No antidote has been identified.
In cases of overdosing, symptomatic treatment is recommended

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Do not contaminate watercourses with the product.

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

DD/MM/YYYY

15. OTHER INFORMATION

PACK SIZES

Translucent high-density polyethylene (HDPE) bottle equipped with an integrating dosing system and two openings sealed with a polyethylene seal closed with a polypropylene screw cap (1L).
Presentation:
Box of a bottle of 1L
The use of this format (1 L) is limited to animals of at least 100Kg

White high-density polyethylene (HDPE) bottle sealed with a wax/polyolefin seal and closed with a white polypropylene screw cap (2.5 and 5L).
Presentation:
Box of a bottle of 2.5 L
Box of a bottle of 5 L

Not all pack sizes may be marketed.