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Epromec 5mg/ml Pour-On Solution for Beef and Dairy Cattle

Species:	Cattle
Therapeutic indication:	**Pharmaceuticals: Endectocides:** For cattle
Active ingredient:	Eprinomectin
Product:	Epromec 5mg/ml Pour-On Solution for Beef and Dairy Cattle
Product index:	Epromec Pour-on for Cattle
Cattle - milk:	Zero hours
Cattle - meat:	15 days
Incorporating:	

Presentation

A clear pour-on solution.

One ml contains Eprinomectin 5mg and Butylated hydroxytoluene (E321) 10 mg

Uses

Treatment of infestations by the following internal and external parasites sensitive to eprinomectin:

Gastrointestinal roundworms (adults and fourth-stage larvae)

Ostertagia spp., *Ostertagia lyrata* (adults only), *Ostertagia ostertagi* (including inhibited L4), *Cooperia* spp. (including inhibited L4), *Cooperia oncophora, Cooperia pectinata, Cooperia punctata, Cooperia surnabada, Haemonchus placei, Trichostrongylus* spp., *Trichostrongylus axei, Trichostrongylus colubriformis, Bunostomun phlebotomum, Nematodirus helvetianus, Oesophagostomum* spp. (adults only), *Oesophagostomum radiatum, Trichuris* spp. (adults only)

Lungworms

Dictyocaulus viviparus (adults and L4)

Warbles (parasitic stages)

Hypoderma bovis, Hypoderma lineatum

Mange Mites

Chorioptes bovis, Sarcoptes scabiei var.*bovis*

Lice

*Damalinia (Bovicola) bovis (*biting lice), *Linognathus vituli* (sucking lice), *Haematopinus eurysternus* (sucking lice), *Solenopotes capillatus* (sucking lice)

Horn flies

Haematobia irritans

Prevention of reinfestations:

The product protects the animals against reinfestations with:

- *Nematodirus helvetianus* for 14 days.
- *Trichostrongylus axei* and *Haemonchus placei* for 21 days.
- *Dictyocaulus viviparus, Cooperia oncophora, Cooperia punctata, Cooperia surnabada, Oesophagostomum radiatum* and *Ostertagia ostertagi* for 28 days.

Dosage and administration

Dosage: Administer only by topical application at the dose rate of 1 ml of the product per 10 kg of body weight, corresponding to the recommended dose rate of 0.5 mg eprinomectin per kg b.w. The product should be applied along the backline in a narrow strip extending from the withers to the tailhead. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible and accuracy of the dosing device should be checked. 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.

All the animals belonging to the same group should be treated at the same time.

Body-weight (kg)	Dose Volume (ml)
Up to 100	10

101 – 150	15
151 – 200	20
201 – 250	25
251 – 300	30

Over 300 kg bodyweight, give 5ml per 50 kg bodyweight

Method of administration:

For the 1L presentation:

The bottle is equipped with an integrated dosing system, and has two openings. One opening is connected to the body of the container and the other to the dispensing chamber (dosing system). Unscrew the tamper-evident cap and remove the seal of the dispensing chamber (integrated dosing system allowing 5 ml to 25 ml doses). Squeeze the bottle to fill the dispensing chamber with the required volume of product.

For the 2.5 L, 3 L and 5 L presentations:

To be used with an appropriate dosing system such as a dosing gun and coupling vented cap. Unscrew the polypropylene cap. 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 should be removed and replaced by the polypropylene cap.

Contra-indications, warnings, etc

Contraindications:

The product is formulated only for topical application for beef and dairy cattle, including lactating dairy cattle.

Do not use in other animal species. Do not administer orally or by injection.

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

Special precautions for use in animals.

For external use only.

For effective use, the product should not be applied to areas of the backline covered with mud or manure.

The product should be applied only on healthy skin.

Not to be used in other species; avermectins can cause fatalities in dogs, especially Collies, Old English Sheepdogs and related breeds and crosses,

and also in turtles/tortoises.

To avoid adverse reactions due to the death of warble larvae in the oesophagus or backbone, it is recommended to administer the product after the end of warble fly activity and before the larvae reach their resting sites in the body; consult a veterinary surgeon regarding the appropriate time for treatment.

Rainfall at any time before or after treatment will not affect the efficacy of the product.

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

This product may be irritating to human skin and eyes and may cause hypersensitivity.

Avoid direct contact with the skin or eyes. Wear rubber gloves and protective clothing when applying the product. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with water.

Do not smoke, eat or drink while handling the veterinary medicinal product. Wash hands after use. Should clothing become contaminated, remove as soon as

possible and launder before re-use. In the event of ingestion, wash out mouth with water and seek medical advice. People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product.

Special warnings for each target species

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- 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 within the EU. However resistance to other macrocyclic lactones has been reported in parasite species in cattle within the EU. 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.

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.

Use during pregnancy and lactation

Laboratory studies (rat, rabbit) have not produced any evidence of a teratogenic or embryotoxic effects due to the use of eprinomectin at therapeutic doses. The safety of eprinomectin in cattle has been established during pregnancy and lactation and in reproductive bulls. Can be used during pregnancy and lactation as well as in reproductive bulls.

Interaction with other medicinal products and other forms of interaction

Since eprinomectin binds strongly to plasma proteins, this should be taken into account if it is used in association with other molecules having the same characteristics.

Overdose (symptoms, emergency procedures, antidotes), if necessary

No signs of toxicity appeared when 8-week old calves were treated at up to 5 times the therapeutic dose (2.5 mg Eprinomectin/kg body weight) 3 times at 7-day intervals. One calf treated once at 10 times the therapeutic dose (5 mg/kg body weight) in the tolerance study showed transient mydriasis. There were no other adverse reactions to treatment. No antidote has been identified.

Other precautions

Eprinomectin is very toxic to dung fauna and aquatic organisms, is persistent in soils and may accumulate in sediments. The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of eprinomectin (and products of the same anthelmintic class) in cattle. The risk to aquatic ecosystems will be further reduced by keeping treated cattle away from water bodies for three weeks after treatment.

Withdrawal period

Meat and Offal: 15 days

Milk: Zero hours

Adverse reactions (frequency and seriousness)

Pruritus and alopecia have been observed after the use of the veterinary medicinal product in very rare cases.

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).

Pharmaceutical precautions

For Squeeze pour containers (1 L): Keep the container in the outer container in order to protect from light.

For Flexi-pack containers (2.5 L, 3 L and 5 L): Protect from light.

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

Discard 6 months after first opening.

Extremely dangerous to fish and aquatic life. Do not contaminate lakes or waterways with the product or used containers. Any unused veterinary medicinal product or waste material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Legal category

Legal category: POM-VPS

Packaging quantities

1L, 2.5L, 3L and 5L.

Not all pack sizes may be marketed.

Marketing Authorisation Holder (if different from distributor)

N/A

Further information

N/A

Marketing Authorisation Number

Vm 08749/4059

Significant changes

GTIN

GTIN description: 1 litre, 3 litre, 5 litre

GTIN: --