



Solution for injection



COMPOSITION

Eprinomectin	20.0 mg
Excipients q.s.	1.0 ml

PROPERTIES

Eprinomectin is a member of the macrocyclic lactone class of endectocides. Compounds of the class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve or muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite.

Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).

The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels; the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels, and they do not readily cross the blood-brain barrier.

TARGET SPECIES AND INDICATIONS

Eprecis[®] is indicated for cattle.

The indications for use are:

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

	Adult	L4	Inhibited L4
Gastrointestinal roundworms			
<i>Ostertagia ostertagi</i>	•	•	•
<i>Ostertagia lyrata</i>	•		
<i>Ostertagia</i> spp.	•	•	
<i>Cooperia oncophora</i>	•	•	
<i>Cooperia pectinata</i>	•	•	
<i>Cooperia surnabada</i>	•	•	
<i>Cooperia punctata</i>	•	•	
<i>Cooperia</i> spp.	•	•	•
<i>Haemonchus placei</i>	•	•	
<i>Trichostrongylus axei</i>	•	•	
<i>Trichostrongylus colubriformis</i>	•	•	
<i>Trichostrongylus</i> spp.	•	•	
<i>Bunostomum phlebotomum</i>	•	•	
<i>Nematodirus helvetianus</i>	•	•	
<i>Oesophagostomum radiatum</i>	•	•	
<i>Oesophagostomum</i> spp.	•		
<i>Trichuris</i> spp.	•		
Lungworms			
<i>Dictyocaulus viviparus</i>	•	•	

Sucking lice: *Haematopinus eurysternus*, *Linognathus vituli*, *Solenopotes capillatus*

Horn flies: *Haematobia irritans*

Warbles (parasitic stages): *Hypoderma bovis*, *Hypoderma lineatum*

Mange mites: *Sarcoptes scabiei* var. *bovis*

Prevention of reinfestations:

The product protects treated animals against reinfestations with:

- *Trichostrongylus* spp. (including *Trichostrongylus axei* and *Trichostrongylus colubriformis*), *Haemonchus placei*, *Cooperia* spp. (including *Cooperia oncophora*, *Cooperia punctata*, *Cooperia surnabada*), *Dictyocaulus viviparus*, *Oesophagostomum radiatum*, *Ostertagia* spp. (including *Ostertagia ostertagi* and *Ostertagia lyrata*) and *Nematodirus helvetianus* for 14 days.

- *Haematobia irritans* for at least 7 days.

DOSAGE AND ADMINISTRATION

Subcutaneous use.

Single administration of 0.2 mg of eprinomectin per kg bodyweight; corresponding to 1 ml of the veterinary medicinal product per 100 kg bodyweight.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible and accuracy of the dosing device should be checked.

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Do not exceed 30 broachings per vial for 50 and 100 ml and 20 broachings for 250 and 500 ml. If more broachings than recommended are required, draw off needle should be used.

CONTRAINDICATION

Do not use in other animal species. Do not use in case of hypersensitivity to active substance or to any of the excipients. Do not administer orally or by intramuscular or by intravenous injection.

WITHDRAWAL PERIOD: Meat and offal: 63 days. Milk: zero hours.

WARNINGS AND PRECAUTIONS

a) Special warnings for 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.
- 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.

Cattle:

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.

b) Special precautions for use

i) Special precautions for use in animals:

- Usual aseptic procedures for administration of a parenteral injection should be followed.
 - 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.
 - 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.
- ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals
- People with known hypersensitivity to eprinomectin or to any of the excipients should avoid contact with the veterinary medicinal product
 - The veterinary medicinal product causes serious eye irritation. Avoid contact with the eyes. Wash any splashes from eyes immediately with water.
 - This product may cause neurotoxicity. Care should be taken when handling the product to avoid self-injection. In case of accidental injection, seek medical advice immediately and show the package leaflet or the label to the physician.
 - Avoid contact with the skin. Wash any splashes from skin immediately with water.
 - Avoid oral exposure. Do not eat, drink or smoke while handling the veterinary medicinal product.
 - Wash hands after use.
 - The excipient glycerol formal may cause harm to the unborn child. In addition, the active substance eprinomectin can be transferred to breast milk. Pregnant/breast-feeding women and women of childbearing age should therefore avoid exposure to this product.

c) 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 two to five weeks after treatment.

INTERACTIONS WITH OTHER MEDICAMENTS

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.

PREGNANCY AND LACTATION: Can be used during pregnancy and lactation.

SIDE EFFECTS

Following treatment, moderate to severe swelling at the site of injection is very common. Typically, the swelling resolves within 7 days, but induration (hardness) may persist for in excess of 21 days. Swelling may be associated with mild to moderate pain.

This reaction disappears without any treatment and does not impair the safety or efficacy of the veterinary medicinal product.

SYMPTOMS AND TREATMENT OF OVERDOSE

After subcutaneous administration of up to 5 times the recommended dose, no adverse events were observed except a transient reaction (swelling followed by induration) at the injection site.

STORAGE

Store below 30°C (Room Temperature). Once broached, it can be used within 6 months.

Keep out of reach of children.

PACKAGING SIZES: 100 ml & 250 ml.

Registered by:

Ceva Animal Health Malaysia Sdn Bhd - 27-2, Oval Damansara.
No. 685, Jalan Damansara 60000 Kuala Lumpur.

Mfd by:

Ceva Santé Animale - 10 Avenue de La Ballastière - 33500 Libourne - France

FOR VETERINARY USE ONLY

Date of Revision of Package Insert:

NOT EPRECIS MALAISIE
200x160/FP 35,5x160
Recto/Verso
CODE ARTICLE : 00000
Black

EPRECIS MALAISIE

ID : 71736

CORPS : 7 pts

VALERIE 02/07/21 - 04/08/21 - 24/08/21