

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nullamec 5 mg/ml pour-on solution for cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of solution contains:

Active substance:

Eprinomectin 5.00 mg

Excipients:

Butylhydroxytoluene (E 321) 0.10 mg

All-rac-alpha-tocopherol (E 307) 0.06 mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pour-on solution.

Pale yellow to yellow clear solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle (beef and dairy cattle).

4.2 Indications for use, specifying the target species

Treatment of infestations by the following parasites sensitive to eprinomectin:

Cattle:

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

- Warbles (parasitic stages):

Hypoderma bovis

Hypoderma lineatum

- Mange mites:

Chorioptes bovis

Sarcoptes scabiei var. *Bovis*

- Sucking lice:

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus

- Biting lice:

Bovicola (Damalinia) bovis

- Horn flies:

Haematobia irritans

The product protects the animals against reinfestations with:

- *Nematodirus helvetianus* for 14 days.

- *Trichostrongylus axei* for 21 days.

- *Dictyocaulus viviparus*, *Haemonchus placei*, *Cooperia oncophora*, *Cooperia punctata*, *Cooperia surnabada*, *Oesophagostomum radiatum* and *Ostertagia ostertagi* for 28 days.

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.

4.3 Contraindications

Avermectins may not be well tolerated in non-target species (including dogs, cats and horses). Cases of mortality are reported in dogs, especially Collies, bobtail and related breeds and crosses, and also in turtles/tortoises.

Do not use in other animal species.

Do not administer orally or by injection.

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

4.4 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 in cattle 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 planned programme to control both internal and external parasites of cattle based on the epidemiology of these parasites.

4.5 Special precautions for use

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.

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 to know the appropriate treatment period.

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

- This product may be irritating to the skin and eyes and may cause hypersensitivity (allergic reactions).
- Avoid contact with the skin and eyes during treatment and when handling recently treated animals.
- People with known hypersensitivity to eprinomectin should avoid contact with the product.
- Wear rubber gloves, boots and a waterproof coat when applying the product. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water.
- Should clothing become contaminated, remove as soon as possible and launder before re-use.
- This product may affect the central nervous system if accidentally ingested. Avoid accidental ingestion of the product, including by hand to mouth contact. If ingestion does occur, wash the mouth out with water and seek medical advice.
- Do not smoke, eat or drink while handling the product.
- Wash hands after use.

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 fly 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.

4.6 Adverse reactions (frequency and seriousness)

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 reactions)
- 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)

4.7 Use during pregnancy, lactation or lay

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 the veterinary medicinal product 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.

4.8 Interaction with other medicinal products and other forms of interactions

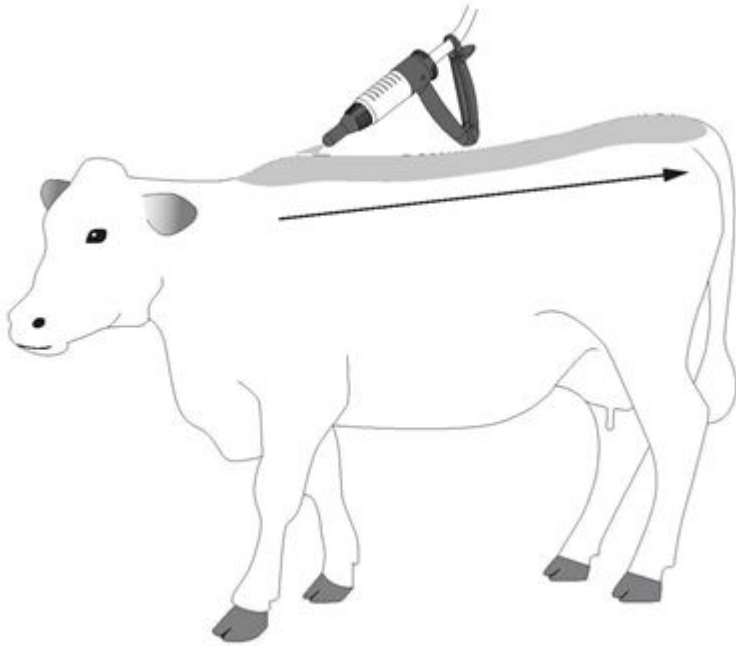
Since eprinomectin binds strongly to plasma proteins, this should be taken into account if it is used in association with other molecules having the same characteristics.

4.9 Amounts to be administered and administration route

Pour-on use.

To be administered topically in one single treatment 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 tail head.



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

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- or over-dosing.

Method of Administration:

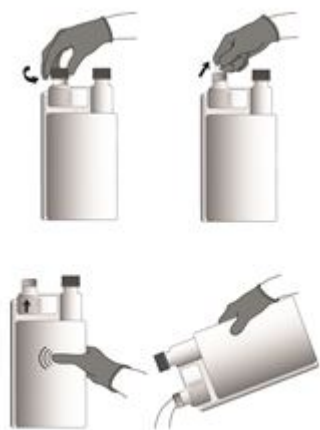
For the 1 litre presentation:

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 cap and remove the seal of the dispensing chamber (integrated dosing system allowing 10-ml doses and 50-ml doses).

Squeeze the bottle to fill the dispensing chamber with the required volume of product.

Figure1 Use of the graduated chamber on the 1litre containers:



For the 2.5 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 (PP) simple cap. Remove the protective seal from the bottle. Screw the coupling vented cap on the bottle and make sure it is tightened. Connect the other side to a dosing gun.

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

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

Vented caps should be placed for a later use in the cardboard box.

Figure 2 Attaching the recommended dosing gun to the 2.5 and 5 litre containers:



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

No signs of toxicity have been observed after administration of up to 5 times the recommended dose. No specific antidote has been identified.

4.11 Withdrawal period(s)

Meat and offal: 15 days.

Milk: zero hours.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: endectocides, macrocyclic lactones, avermectins.

ATCvet code: QP54AA04.

5.1 Pharmacodynamic properties

Eprinomectin is a molecule with an endectocidal activity belonging to the macrocyclic lactone class. Compounds of the class bind with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve or muscle cells. These compounds bind selectively to these channels, which 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 GABA (gamma-aminobutyric acid).

5.2 Pharmacokinetic particulars

The bioavailability of topically applied eprinomectin in cattle is about 30% with most absorption occurring by about 10 days after treatment. Eprinomectin is strongly linked to plasma proteins (99%). Eprinomectin is not extensively metabolized in cattle following topical administration.

Faeces are the major route of elimination.

Environmental properties

Like other macrocyclic lactones, eprinomectin has the potential to adversely affect non-target organisms (See section 4.5 other precautions).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E321)

all-rac-alpha-tocopherol (E307)

Propylene glycol dicaprylocaprate

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the immediate packaging: 18 months and before expiry date.

6.4 Special precautions for storage

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

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

Once opened the bottles have to be kept upright.

6.5 Nature and composition of immediate packaging

- Squeeze-measure pour-on system:

1 L natural high density polyethylene (HDPE) bottle with integrated measuring chamber graduated each 10 ml up to 50 ml, removable aluminium/PE seals and HDPE screw cap included in a cardboard box.

- Back pack:

2.5 L and 5 L white HDPE bottles with a removable (ethylene-methacrylic acid) zinc co-polymer seal, a polypropylene (PP) screw cap and a PP coupling vented cap included in a cardboard box.

Pack sizes: 1L, 2.5L, 5L, 7.5L (3x2.5L), 10.0L (2x5L) 12.5L (2x5L+1x2.5L) and 15.0L (3x5L).

Box of 1L bottle.

Box of 2.5L bottle.

Box of 5L bottle.

Box of 7.5L (3x2.5L), package contains three 2.5L presentation and a pour on dosing gun.

Box of 10L (2x5L), package contains two 5L presentation and a pour on dosing gun.

Box of 12.5L (2x5L+ 1x2.5L), package contains two 5L presentation, one 2,5L presentation and a pour on dosing gun.

The dosing gun includes PVC tubing and a plastic dosing chamber.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

The veterinary medicinal product is dangerous for fish and aquatic organisms. Do not contaminate surface waters or ditches with the product or used container.

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

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
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Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/066/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First date of authorisation: 14 June 2018

10 DATE OF REVISION OF THE TEXT

June 2019