

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Unomec 5 mg/ml Pour-on Solution for Beef and Dairy Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Eprinomectin 5.0 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylated hydroxytoluene (E321)	10 mg
Propylene glycol dicaprylocaprate	

Clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle (beef and dairy cattle).

3.2 Indications for use for each target species

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

Bunostomum 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 veterinary medicinal 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.

3.3 Contraindications

Do not administer orally or by injection. The veterinary medicinal 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 use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

For external use only.

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

The veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product.

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

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

Avoid direct contact with the skin or eyes.

Personal protective equipment consisting of rubber gloves and protective clothing should be worn when handling the veterinary medicinal 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 eprinomectin should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

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 veterinary medicinal 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.

Other precautions:

Avermectins can cause fatalities in dogs, especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.

3.6 Adverse events

Cattle (beef and dairy cattle)

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Application site alopecia Application site pruritus
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Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy, lactation and fertility:

Laboratory studies in rats and rabbits have not produced any evidence of 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 and in reproductive bulls.

3.8 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.

3.9 Administration routes and dosage

Pour-on use.

Administer only by topical application at the dose rate of 1 ml of the veterinary medicinal product per 10 kg of body weight, corresponding to the recommended dose rate of 0.5 mg eprinomectin per kg body weight.

The veterinary medicinal product should be applied along the backline in a narrow strip extending from the withers to the tailhead.

To ensure a correct dosage, 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.

Method of administration:

For the 1 L 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 veterinary medicinal 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 removed and replaced by the polypropylene cap.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No signs of toxicity appeared when 8-week-old calves were treated at up to 5x the therapeutic dose (2.5 mg eprinomectin/kg body weight) 3 times at 7-day intervals.

One calf treated once at 10x 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and Offal: 15 days.

Milk: Zero hours.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP54AA04.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

Maximum plasma concentration

In beef cattle treated topically with radiolabeled eprinomectin at the recommended dose of 0.5 mg/kg bodyweight, there was no distinct peak in the plasma radioactivity versus time curve, but a broad plateau occurred between 9 and 14 days after dosing. Highest concentrations of eprinomectin B1a were in the range of 7.33 - 19.74 ng/ml.

In lactating dairy cows treated topically with 0.75 mg radiolabeled eprinomectin/kg bodyweight, some animals showed a distinct peak in plasma radioactivity levels, whereas others exhibited a broad

plateau. Peak levels of eprinomectin B1a were in the range of 42.7 - 134.4 ng/ml. The highest levels of plasma radioactivity occurred between one and 7 days after dosing.

Metabolism

The bioavailability of topically applied eprinomectin in cattle is about 30% with most absorption occurring by about 10 days after treatment. Eprinomectin is not extensively metabolized in cattle following topical administration. In all biological matrices, the B1a component of eprinomectin is the single most abundant residue.

The contribution of eprinomectin B1a to the total radioresidue level remained relatively constant between 7 days and 28 days after treatment - for example, between 84% and 90% in liver, the proposed principal target tissue.

Excretion

Faeces were the major route of elimination of the drug in beef cattle and dairy cows.

In beef cattle, faeces and urine were collected from 2 steers, and the amount of drug excreted up to 28 days after dosing was determined as 15 - 17% and 0.25 % in faeces and urine, respectively. A further 53 - 56% of the dose was recovered from the skin at the application site collected from 3 animals sacrificed at 28 days after dosing.

Environmental properties

Like other macrocyclic lactones, eprinomectin has the potential to adversely affect non-target organisms. Following treatment, excretion of potentially toxic levels of eprinomectin may take place over a period of several weeks. Faeces containing eprinomectin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation. Eprinomectin is very toxic to aquatic organisms, is persistent in soils and may accumulate in sediments.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 36 months.

Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

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 5L): Protect from light.

5.4 Nature and composition of immediate packaging

High density polyethylene container with a polypropylene tamper evident screw cap which consists of the following:

1 L 'Squeeze pour' packs.

2.5 L, 3 L and 5 L 'Flexi' packs.

Pack sizes: 1 L, 2.5 L, 3 L and 5 L.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as eprinomectin is extremely dangerous for fish and other aquatic organisms. Do not contaminate lakes or waterways with the veterinary medicinal product or used containers.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/110/001

8. DATE OF FIRST AUTHORISATION

15/05/2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

20/03/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary)