SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eprinex Pour-on for Beef and Dairy Cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance
Eprinomectin 5.0 mg

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxytoluene (E321)	0.1 mg
Propylene glycol octanoate decanoate	

Clear, slightly yellow pour-on solution

3. CLINICAL INFORMATION

3.1 Target species

Cattle (beef and dairy cattle).

3.2 Indications for use for each target species

Indicated for treatment and control of the following parasites:

Parasite	**Adult**	**L4**	**Inhibited L4**
Gastrointestinal roundworms:			
Ostertagia spp.	◆	◆	
Ostertagia lyrata	◆		
Ostertagia ostertagi	◆	◆	◆
Cooperia spp.	◆	◆	◆
Cooperia oncophora	◆	◆	
Cooperia pectinata	◆	◆	
Cooperia punctata	◆	◆	
Cooperia surnabada	◆	◆	
Haemonchus placei	◆	◆	
Trichostrongylus spp.	◆	◆	
Trichostrongylus axei	◆	◆	
Trichostrongylus colubriformis	◆	◆	
Bunostomum phlebotomum	◆	◆	
Nematodirus helvetianus	◆	◆	
Oesophagostomum spp.	◆		

Oesophagostomum radiatum	◆	◆
Trichuris spp.	◆	
Lungworms		
Dictyocaulus viviparus	◆	◆
Warbles (parasitic stages)		
Hypoderma bovis		
H. lineatum		
Mange Mites		
Chorioptes bovis		
Sarcoptes scabiei		
Lice		
Damalinia bovis (biting lice)		
Linognathus vituli (sucking lice)		
Haematopinus eurysternus (sucking lice)		
Solenopotes capillatus (sucking lice)		

Prolonged Activity: applied as recommended, the veterinary medicinal product controls reinfections with:

Parasite*	Prolonged Activity
Dictyocaulus viviparus	up to 28 days
Ostertagia spp.	up to 28 days
Oesophagostomum radiatum	up to 28 days
Cooperia spp.	up to 21 days
Trichostrongylus spp	up to 21 days
Haemonchus placei	up to 14 days
Nematodirus helvetianus	up to 14 days

* The following parasite species are included within each of the relevant genera:
Ostertagia ostertagi, O. lyrata, Cooperia oncophora, C. punctata, C. surnabada, Trichostrongylus axei, T. colubriformis.

For 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.

3.3 Contraindications

This veterinary medicinal product is formulated only for topical application to beef and dairy cattle, including lactating dairy cattle.

Do not use in other animal species. Avermectins can cause fatalities in dogs, especially Collies, Old English Sheepdogs and related breeds and crosses, and also in turtles/tortoises.
Do not administer orally or by injection.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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

Unnecessary use of antiparasitic or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each herd.
Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development. Within a herd, maintenance of susceptible refugia is essential to reduce that risk. Systematically applied interval-based treatment and treatment of a whole herd should be avoided. Instead, if feasible, only selected individual animals or subgroups should be treated (targeted selective treatment). This should be combined with appropriate husbandry and pasture management measures. Guidance for each specific herd should be sought from the responsible veterinarian.

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. Confirmed resistance should be reported to the marketing authorisation holder or to the competent authorities.

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 nematode populations in cattle within the EU, which may be associated with side-resistance to eprinomectin. The use of this veterinary medicinal product should take into account local information about susceptibility of target parasites, where available.

While mite and louse numbers decline rapidly following treatment, due to the feeding habits of some mites, in some cases several weeks may be required for complete eradication.

3.5 Special precautions for use

Special precautions for safe use in the target species:

For external use only.
The veterinary medicinal product should be applied only on healthy skin.

To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or in the spine, it is recommended to administer the veterinary medicinal product at the end of warble fly activity and before the larvae reach their resting sites.

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.
- This veterinary medicinal product may be irritating to skin and eyes and may cause hypersensitivity.
- Avoid skin and eye contact with the veterinary medicinal product during treatment and when handling recently treated animals.
- Personal protective equipment consisting of rubber gloves, boots and a waterproof coat should be worn when handling the veterinary medicinal product.
- Should clothing become contaminated, remove as soon as possible and launder before re-use.
- In case of accidental spillage onto skin, wash the affected area immediately with soap and water and water, and seek medical advice immediately and show the package leaflet or the label to the physician.
- In case of accidental eye exposure, flush eyes immediately with water, and seek medical advice show the package leaflet or the label to the physician .
- This product may be toxic after accidental ingestion. Avoid accidental ingestion of the product by hand to mouth contact.
- Do not smoke, eat or drink while handling the product.
- In the event of accidental ingestion, wash out mouth with water and seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands after use.

Other 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 repeated use of eprinomectin (and products of the same anthelmintic class).
In order to reduce the risk to aquatic ecosystems, treated animals should not have direct access to water bodies for two to five weeks after treatment.

3.6 Adverse events

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Pruritus, alopecia

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.
Studies have demonstrated a wide safety margin.
Studies conducted at three times the recommended use level of 0.5 mg/kg bodyweight of eprinomectin had no adverse effect on breeding performance of cows or bulls.

Lactation:
May be used in dairy cattle during all stages of lactation.

3.8 Interaction with other medicinal products and other forms of interaction

No interactions with other medicines and no other forms of interactions are known.
Since eprinomectin binds extensively 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.
For single application only.

To ensure a correct dosage, bodyweight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.
If animals are to be treated collectively rather than individually, reasonable homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one. Underdosing could result in ineffective use and may favour resistance development.

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

Method of administration:
The veterinary medicinal product should be applied topically by pouring along the backline in a narrow strip extending from the withers to the tailhead.

For 250 ml and 1 litre bottles:
Attach the dose dispenser to the bottle. Set the dose by turning the top section of the dose dispenser to align the correct bodyweight with the pointer inside the dose dispenser. When bodyweight is between markings, use the higher setting.
Hold the bottle upright and squeeze it to deliver a slight excess of the required dose as indicated by the calibration lines.
By releasing the pressure, the dose automatically adjusts to the correct level. Tilt the bottle to deliver the dose. For the 1 litre bottle: when a 10 ml or 15 ml dose is required, turn the pointer to ‘’STOP’’ before delivering the dose. The off (STOP) position will close the system between dosing.

The dose dispenser should not be stored attached to the bottle when not in use. Remove the dose dispenser after each use and replace with the bottle cap.

For 2.5 and 5 litre backpacks:
Connect the dosing gun and draw-off tubing to the backpack as follows:
Attach the open end of the draw-off tubing to an appropriate dosing gun.
Attach draw-off tubing to the cap with the stem that is included in the pack. Replace shipping cap with the cap having the draw-off tubing. Tighten the draw-off cap.
Gently prime the dosing gun, checking for leaks.
Follow the dosing gun manufacturer's directions for adjusting the dose and proper use and maintenance of the dosing gun and draw-off tubing.

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 5 times the therapeutic dose (2.5 mg/kg bodyweight of eprinomectin/kg) 3 times at 7-day intervals.

One calf treated once at 10 times the therapeutic dose (5 mg/kg b.w.) in the tolerance study showed transient mydriasis. There were no other adverse reactions to the 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 which have a unique mode of action. 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.

5.2 Pharmacokinetics

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 metabolised in cattle following topical administration. In all biological matrices, the B_{1a} component of eprinomectin is the single most abundant residue. Eprinomectin consists of the components B_{1a} (≥ 90%) and B_{1b} (≤ 10%) which differ by a methylene unit and is not extensively metabolized in cattle. Metabolites amount to approximately 10% of the total residues in plasma, milk, edible tissues and faeces.

The metabolism profile is nearly identical, qualitatively and quantitatively, in the above biological matrices and does not change significantly with time after administration of eprinomectin. The percent contribution of B_{1a} and B_{1b} to the overall metabolite profile remains constant. The ratio of the two drug components in the biological matrices is identical to that in the formulation demonstrating that the two eprinomectin components are metabolized with nearly equal rate constants. Since the metabolism and the tissue distribution of the two components are quite similar, the pharmacokinetics of the two components would be also similar.

Since the two components of the closely related avermectin and ivermectin were found to be equally efficacious, it may be concluded that this also applies to the two eprinomectin components.

The contribution of eprinomectin B_{1a} to the total radio residue 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.

Maximum plasma concentration

Pharmacokinetic studies were conducted in nongravid, nonlactating dairy cows which were dosed with eprinomectin by i.v. (25, 50, and 100 mcg/kg doses) and topical (500 mcg/kg) routes in a cross-over design. The plasma clearance was independent of i.v. dose, indicating that the plasma concentration increased proportionally to the dose. Following topical administration, peak plasma concentrations of 22.5 ng/mL (range 17.2 - 31.9 ng/mL) were observed 2 - 5 days postdose. Bioavailability of eprinomectin by the topical route was 0.29 (range 0.21 - 0.36).
Most of the drug absorption occurred within 7 - 10 days post dose.
The mean residence time (the average time it takes the animal to clear the drug from the time of absorption) of topically administered eprinomectin was calculated to be 165 hours.

Tissue residues
The level of total residues in tissues of beef cattle and lactating dairy cows was of the same order with liver > kidney > fat > muscle.
The distribution of total residue in edible tissues differs from that seen with other macrocyclic lactones such as abamectin and ivermectin. For these compounds, residue concentrations in fat were much closer to those in liver, and fat contained significantly higher total residue concentrations than kidney, whereas the eprinomectin residue concentrations in fat were much lower than those in liver and kidney.
The half-life for depletion of total residue was about 8 days for all 4 tissues in cattle. Eprinomectin B_{1a} concentration depleted at a similar rate to that of total residue.

Milk residues
Twenty dairy cows were treated with unlabelled eprinomectin at the recommended dose of 0.5 mg/kg of bodyweight. The maximum concentration of eprinomectin B_{1a} in milk ranged from < 2.3 ng/ml (the limit of quantitation) to 11.36 ng/ml, with the peak occurring 2-3 days after treatment in most of the animals.

Excretion
Faeces was 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 0.35% 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:
3 years.

5.3 Special precautions for storage

Keep the bottle or backpack in the outer carton in order to protect from light. This veterinary medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

250 ml and 1 litre HDPE bottle.
2.5 litre and 5 litre HDPE backpack.
Sealed foiled and tamper evident screw cap with polypropylene liner.

250 ml bottle with a dose dispenser of 25 ml.
1 litre bottle with a dose dispenser of 60 ml.

One bottle or one backpack per cardboard box.
The 2.5 litre and 5 litre backpacks are designed for use with a suitable automatic dispensing gun.
Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

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

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBERS

Vm 61700/5012
Vm 61700/3016

8. DATE OF FIRST AUTHORISATION

02 July 1997

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

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 28 November 2025