

Leaflet

For Veterinary Use Only
VILMECTIN
Solution For Injection
Veterinary Endectocide

COMPOSITION

Ivermectin is a colorless solution containing 10 mg ivermectin per ml.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Ivermectin is a macrocyclic lactone derivative and exerts its effect by inhibiting nerve transmissions. It binds with high selectivity to glutamate-gated chloride ion channels in parasites. As a result, the permeability of cell membranes to chloride ions increases, causing hyperpolarization in nerve or muscle cells, leading to paralysis and ultimately death. Compounds in this class interact with ligand-gated chloride channels through neurotransmitter transport channels such as GABA. In mammals, its safety is due to the absence of glutamate-gated chloride channels in mammalian cells. Macrocyclic lactones have a low affinity for ligand-gated chloride channels in mammals and cannot easily cross the blood-brain barrier.

Pharmacokinetics Properties

Following administration in cattle, it reaches peak plasma levels (C_{max} : 51 ng/ml) in 43 hours, with a half-life of 129 hours (AUC: 7398 ng h/ml).

Following administration in sheep, it reaches peak plasma levels (C_{max} : 14 ng/ml) in 202 hours, with a half-life of 380 hours (AUC: 4686 ng h/ml).

Only 2% of ivermectin is excreted in the urine, the main route of excretion is gaita. After administration, it is highest in the liver and adipose tissue and lowest in the brain.

The residual antiparasitic effect in cattle is due to its long half-life and 90% binding to proteins.

AREA OF USE/INDICATIONS

Cattle;

It is used in the treatment of the following internal and external parasites:

-Gastrointestinal nematodes:

Ostertagia ostertagi (adult; L3 larvae; L4 larvae, including hypobiosis)

Ostertagia lyrata (adult and L4 larvae)

Haemonchus placei (adult; L3 and L4 larvae)

Trichostrongylus spp. (adult, L4 larvae)

Cooperia spp. (adult, L3 and L4 larvae)

Oesophagostomum radiatum (adult; L3 and L4 larvae)

Nematodirus spp. (adult)

Bunostomum phlebotomum (adult; L3 and L4 larvae)

Strongyloides papillosus (adult)

Trichuris spp. (adult)

Toxocara vitulorum (adult)

-Lung nematodes (adult and 4th stage larvae):

Dictyocaulus viviparus

-Subcutaneous nematodes:

Parafilaria bovicola (adult)

-Eye nematodes:

Thelazia spp. (adult)

-Nocturnal agents (larval stage):

Hypoderma bovis

H. lineatum

Dermatobia hominis

Chrysomya bezziana

-Mange:

Psoroptes ovis

Sarcoptes scabiei var. *bovis*

-Lice:

Linognathus vituli

Haematopinus eurysternus

Solenopotes capillatus

-Ticks:

Ornithodoros savignyi

Boophilus microplus

Boophilus decoloratus

Ivermectin can be used to control *Damalinia bovis* and *Chorioptes bovis*, but complete elimination may not be possible.

The recommended dosage of this product can prevent re-infection for the following periods:

Haemonchus placei, *Cooperia oncophora*, *Cooperia pectinata*, and *Trichostrongylus axei* for 14 days

Ostertagia ostertagi and *Oesophagostomum radiatum* for 21 days

Dictyocaulus viviparus for 28 days

The timing of the treatment may vary depending on epidemiological factors and the characteristics of the farm. The treatment schedule should be assessed by the veterinarian.

For a lasting effect, it is recommended to treat all animals in the 3rd, 8th and 13th weeks after pasture entry.

Sheep;

- Gastrointestinal nematodes:

Haemonchus contortus (adult, L3 larva (including hypobiosis) and L4 larva)

Teladorsagia (Ostertagia) circumcincta (adult, larva L3 (including hypobiosis) and larva L4)

Teladorsagia (Ostertagia) trifurcata (adult and larva L4)

Trichostrongylus axei (adult)

Trichostrongylus colubriformis (adult, larva L3 and L4)

Trichostrongylus vitrinus (adult)

Cooperia curticei (adult and larva L4)
Oesophagostomum columbianum (adult, L3 and L4 larva)
Oesophagostomum venulosum (adult)
Nematodirus filicollis (adult and L4 larva)
Nematodirus spathiger (adult, L3 and L4 larva)
Strongyloides papillosus (adult, L3 and L4 larva)
Trichuris ovis (adult)
Chabertia ovina (adult, L3 and L4 larva)

- Lung nematodes:

Dictyocaulus filaria (adult and L4 larva)
Protostrongylus rufescens (adult)

-Mange:

Psoroptes communis var. ovis
Sarcoptes scabiei
Psorergates ovis

*A single injection significantly reduces the number of *Psoroptes communis var. ovis* and usually leads to resolution of clinical signs of scabies. For complete eradication of live mites, two injections are given 7 days apart.

-Nose nematodes:

Oestrus ovis (all larval stages)

-Lice

Melophagus ovinus

USAGE AND DOSAGE

It is administered as a single dose except in the treatment of *Psoroptes ovis*.

For correct dosing, the body weight of the animals should be measured as accurately as possible. The accuracy of the dosing device should be checked.

If herd treatment is to be applied, animals should be grouped appropriately to avoid over or under dosing.

Cattle: 1 ml for 50 kg body weight (200 µg/kg body weight ivermectin).

Application: Administer subcutaneously in the front or rear of the shoulder area, following aseptic technique. A sterile 1.4 x 15 mm (17G x ½ inch) needle is recommended.

Sheep: 0,5 ml for 25 kg body weight (200 µg/kg body weight ivermectin).

Application: It is administered following aseptic technique for digestive system nematodes, lung nematodes and nose nematodes. A sterile 1.4 x 15 mm (17G x ½ inch) needle is recommended.

For the treatment of *Psoroptes ovis*, two doses are administered 7 days apart. Injections should be given in different areas.

In lambs weighing less than 20 kg, 0.1 ml of product is administered for every 5 kg body weight. In these animals, injectors capable of delivering 0.1 ml of product are recommended.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES

Due to the risk of resistance development and consequently treatment failure, the following practices should be avoided.

- Frequent and repeated use of the same group of anthelmintics within a short period of time.
- Incorrect calculation of body weight, incorrect administration of the product, or using a miscalibrated dosing device, which can lead to administering less than the required dose.

In cases where resistance to anthelmintics is suspected, appropriate tests should be conducted (e.g., fecal egg count reduction test (FECRT)). If data show that resistance to a specific anthelmintic has developed, another product with a different pharmacological class and mode of action should be used.

Resistance to macrocyclic lactones, including ivermectin, has been reported in sheep to *Teladorsagia*, in lambs to *Ostertagia circumcincta*, and in cattle to *Ostertagia ostertagi* and *Cooperia*. Therefore, this product should be used according to regional (farm-level or broader) epidemiological susceptibility data.

Even if clinical improvement is seen, a single dose is not recommended for the treatment of psoroptic mange in sheep as not all causal agents can be eliminated. *Psoroptis ovis* is a highly contagious external parasite. Due to the fact that the causative agents can survive for up to 15 days after treatment, care should be taken to avoid re-infestation of treated animals. It is important that all animals in contact with infected sheep are treated. Contact between treated and untreated animals should be avoided for at least 7 days after the last treatment.

Since ivermectin is highly bound to plasma proteins, it should be used with caution in animals with diseases or nutritional disorders associated with low plasma protein levels.

Avermectins may not be well tolerated in non-target species. Intolerance events leading to death have been reported in dogs, particularly Collies, Bobtails, Old English Sheepdogs, and closely related or cross-bred breeds, as well as in turtles.

Do not combine with lungworm vaccines. If the product is to be applied to vaccinated animals, it should be administered 28 days before or after vaccination.

The excretion of nematode eggs may continue for some time after treatment.

In cattle, to avoid secondary reactions caused by the death of *Hypoderma* larvae in the esophagus and spine, the product is recommended to be applied at the final stage of the fly larvae, before they reach these areas. The death of *Hypoderma lineatum* in the peri-esophageal tissue may cause salivation and tympany. The death of *Hypoderma bovis* in the spinal canal may lead to paresis or paralysis.

Clean the bottle before each use.

Use during pregnancy and lactation: This product can be used in pregnant cattle and sheep. For detailed information regarding its use during lactation, refer to the “*Contraindications*” and “*Withdrawal periods*” sections. The product has no negative effect on fertility.

ADVERSE EFFECTS

In some animals, discomfort may occur after subcutaneous administration. In cattle, this manifests as jumping and rolling. These behaviors typically return to normal within 15 minutes after administration. Hardening and swelling may be observed at the injection site. These reactions are temporary and will disappear within 1-4 weeks.

Very rarely allergic and anaphylactic reactions may occur. These reactions may be accompanied by nervous symptoms such as ataxia, convulsions and/or tremor.

DRUG INTERACTIONS

Do not combine with lungworm vaccines. If the product is to be applied to vaccinated animals, it should be administered 28 days before or after vaccination.

Do not mix with other medicinal products

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

Clinical symptoms of ivermectin toxicity in cattle are ataxia and depression (at 20 times the recommended dose). There is no antidote. In case of overdose, symptomatic treatment should be administered. No signs of toxicity were observed at 3 times the recommended dose. At 100 times the recommended dose, non-fatal ataxia, bilateral mydriasis, dyspnea and somnolence were observed in pigs.

Overdose in sheep may cause ataxia and depression. No systemic toxic effects were observed at twice the recommended dose. In case of overdose, symptomatic treatment can be applied.

WITHDRAWAL PERIODS

Meat: 49 days for cattle, 42 days for sheep. It is not used in cows and sheep from which milk is obtained for human consumption. It should not be used in pregnant cows and sheep within 60 days before parturition.

CONTRAINDICATIONS

It is not administered intravenously or intramuscularly. Due to potential serious side effects, it is not used in other species, especially in cats and dogs. It should not be used in animals known to be sensitive to its components.

GENERAL WARNINGS

Consult a veterinarian before use and if any unexpected effects are observed. Keep out of reach of children and away from foodstuffs.

PRECAUTIONS TO BE TAKEN BY THE ADMINISTRATOR AND WARNINGS FOR VETERINARY SURGEON

Do not consume anything, including cigarettes, during the application of the product. Wash your hands after use.

Since it may cause irritation and pain at the injection site, take necessary precautions to prevent accidental injection. In case of accidental self-injection, consult a doctor with the product label and leaflet. Avoid contact with the product. If contact occurs, wash the area thoroughly with water and soap. In case of eye contact, rinse the eye with plenty of water.

STORAGE CONDITIONS AND SHELF LIFE

Before and after opening, the product should be stored in the original packages, protected from light, below 25°C, without refrigeration or freezing. The shelf life is 3 years. After opening, it should be used within 28 days.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES

IT IS HIGHLY TOXIC TO FISH AND AQUATIC LIFE. Products or used product containers must not be disposed of in or near water sources. The product or used product containers must not be disposed of in water sources or areas near these sources.

COMMERCIAL PRESENTATION FORM

20 ml, 50 ml, 100 ml and 250 ml colorless type II vials, stoppers and flip-off caps, with cardboard box.

PLACE AND CONDITIONS OF SALE

It is sold in pharmacies and veterinary clinics with a veterinarian's prescription. (VSP)

APPROVAL DATE OF LEAFLET: 19.12.2024

MARKETING AUTHORIZATION DATE AND NO: 11.11.1997 – 009/0804

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER

VİLSAN Veteriner İlaçları Tic. ve San. A.Ş.

Balıkhisar Mah. Balıkhisar Köy İçi Küme Evleri No:765A Akyurt/Ankara-Türkiye

MANUFACTURER COMPANY

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Made in Türkiye

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