


The changes are as follows:

Item	Previous	New
1. Packaging	1000 ml	500 ml and 1000 ml
2. Revision date	Nov 09, 2016	Sep 09, 2024
3. Company logo	Vemedim Corporation	Vemedim Animal Health
4. Manufacturer and product holder position	Left and right	up and down
5. Layout	One side containing three sections	Two sides, each containing two sections
6. Color of content	Purple	Blue



Liquid pour on

COMPOSITION
Ivermectin5 mg
Exp. qs.....1 ml

DESCRIPTION:
The finished product is a blue transparent solution

PHARMACODYNAMICS
Ivermectin 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 and 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 their mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

PHARMACOKINETICS
Pour-on formulations are used in cattle, as their application is less stressful for handlers and animals. Bioavailability is low and does not exceed 15% of that for SC injection possibly due to wastage or the drug being trapped in the skin and released very slowly over a longer period of time. Thus, the choice of a SC or pour-on route could be important clinically, as topical formulations (with a longer action) would be more effective against most sensitive parasite species (*D. viviparus* or *Oesophagostomum radiatum*), whereas SC administration should be considered for less sensitive nematodes (*Nematodirus helvetianus* or *Trichostrongylus colubriformis*). With topical application, attention should be paid to the animal's licking behaviour. The bioavailability of ivermectin was lower in calves when licking was prevented (19%) compared to when it was not (33%). Thus, with licking, a substantial amount of topically applied ivermectin could access the systemic circulation via oral consumption resulting in subtherapeutic concentrations in untreated and licked animals, which can contribute to the development of resistance.

Following topical application, ivermectin has a longer plasma half-life in cattle prevented from licking (15.1 days) than in those that are permitted to lick themselves (6.4 days); the half-life is also longer than after IV injection (5 days) reflecting slow absorption through the skin, which limits later elimination. 69% of the dose in faeces from lickets after 28 days of treatment, and only 6.6% of the dose in faeces from non-lickers. These results

are consistent with ivermectin transiting directly through the digestive tract into faeces, which contributes greatly to the drug's faecal output.

INDICATION
For the treatment of the following species of gastrointestinal roundworms, lungworms, eye worms, warbles, mites and lice: **Gastro-intestinal roundworms (adults and fourth stage larvae):** *Ostertagia ostertagi* (including inhibited *O. ostertagi*) *Haemonchus placei* *Trichostrongylus axei* *Trichostrongylus colubriformis* *Cooperia* spp *Oesophagostomum radiatum* *Strongyloides papillosus* (adult) **Lungworms (adult and fourth stage larvae):** *Dictyocaulus viviparus* **Eye worms (adult):** *Thelazia spp* **Warbles (parasitic stages):** *Hypoderma bovis* *Hypoderma lineatum* **Mites:** *Chorioptes bovis* (reduction of infestation) *Sarcoptes scabiei* var *bovis*.

Sucking lice: *Lingonathus vituli*, *Haemaphysurysternum*


Biting Lice: *Damaelina bovis*

The product given at the recommended dosage of 500 micrograms/kg bodyweight, has persistent activity against *Trichostrongylus axei* and *Cooperia* spp acquired during the 14 days after treatment, only if the whole herd is treated simultaneously. It also has a persistent activity against *Ostertagia ostertagi* and *Oesophagostomum radiatum* acquired during the first 21 days after treatment and *Dictyocaulus viviparus* (lungworm) acquired during the first 28 days after treatment. It also has a persistent activity on horn flies (*Haemaphysobos* spp) for 28 days after treatment, partial efficacy may last for up to 3.5 days post application. Occasionally variable activity may be observed against *Haemonchus placei* (L4), *Cooperia* spp, *Trichostrongylus axei* and *Trichostrongylus colubriformis*.

ROUTE OF ADMINISTRATION
For single topical administration

RECOMMENDED DOSE
Dosage: 1 ml per 10 kg bodyweight (based on a recommended dose of 0.500 micrograms/kg bodyweight) To ensure administration of a correct dose, bodyweight should be determined as accurately as possible.

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 overdosing.

Administration: Pour-on use. The formulation should be applied along the mid-line of the back in a narrow strip between the withers and tailhead. The product should be used with appropriate dosing equipment. The interval between 2 treatments should be at least 28 days.

CONTRA-INDICATION
Do not use in cases of known hypersensitivity to the active ingredient. The product has been formulated for topical application specifically for cattle. It should not be administered to other species as severe adverse reactions, including fatalities in dogs, may occur.

PREGNANCY AND LACTATION
The product can be used during pregnancy and lactation in the product will not affect the fertility of cows and bulls and can be given to all ages of animals including young calves

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
None known

SIDE EFFECTS
Occasionally slight irritation at the application site may occur. However, usually these irritations rapidly disappear without treatment.

SYMPTOMS AND TREATMENT OF OVERDOSE
No sign of toxicity appeared up to 1.5 mg/kg (3 times the recommended dose rate). No antidote has been identified. The signs of overdose can be trembling, convulsions and coma. In case of overdose symptomatic treatment should be given.

STORAGE
Keep in cool and dry place (below 30°C)

WARNING & PRECAUTION
Special warnings for each target species
Cattle should not be treated when hair or hide is wet. Rain falling on cattle in less than two hours after dosing may result in reduced efficacy. However, the efficacy of the product against established infections of *O. ostertagi* or *D. viviparus* is not adversely affected if the hide is wet or if rain falls shortly after treatment. Do not apply to areas of skin that may have mange scabs or other lesions or to areas contaminated with mud or manure.

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 body weight, misadministration of the product, or lack of calibration of the dosing device. 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.

Resistance to Ivermectin has been reported in *Ostertagia ostertagi* in cattle. Therefore, the use of this product should be based on local (region, farm) epidemiological information about susceptibility of the helminth species and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for use in animals
Ivermectins may not be well tolerated in all non-target species. Cases of intolerance with fatal outcome are reported in dogs, especially Collies. Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises. To avoid secondary reactions due to the death of *Hypoderma* larvae in the oesophagus or in the spine, it is recommended to administer the product at the end of the period of warble fly activity and before the larvae reach their resting site. As Ivermectin is extremely dangerous to fish and aquatic life, treated animals should not have direct access to surface water and ditches during treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
The product may be irritating to human skin and eyes and the user should be careful not to apply it to himself or other persons. Operators should wear rubber gloves and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. Use only in well-ventilated areas or outdoors.

HIGHLY FLAMMABLE
Keep away from heat, spark, open flame or other source of ignition. Do not eat, drink or smoke whilst handling the product. As absorption through skin can occur, in the event of accidental skin contact the affected area should be washed immediately with soap and water.

If accidental eye exposure occurs, flush the eyes immediately with water and seek medical attention. Wash hands after use.

- Keep out of reach of children
- Jauhkan daripada kanak-kanak

SHELF LIFE: 3 years
SHELF LIFE AFTER OPENING: 24 hours
WITHDRAWAL PERIOD:
Meat and offal: 28 days
Milk: Not permitted for use in lactating cattle producing milk for human consumption. Do not use in non-lactating dairy cows including pregnant and lactating cows within 30 days prior to calving.

PACKAGING: 500 ml and 1000 ml
REVISED DATE: Sep 19, 2024

Manufactured by: Vemedim Veterinary Drugs and Probiotics Co. Ltd (Vemedim Animal Health)
Song Hau IZ, Dong Phu Commune, Chau Thanh Dist, Hau Giang Prov, Vietnam

Product Registration Holder: Vemedim Sdn. Bhd.
15, Jalan USJ 1/31, 47600 Subang Jaya, Selangor, Darul Ehsan, Malaysia.