IMECIN 10 MG/ML SOLUTION

FOR ANIMAL USE ONLY

PRODUCT NAME

IMECIN 10 MG/ML SOLUTION

NAME AND STRENGTH OF ACTIVE INGREDIENT

Each ml contains Ivermectin 10 mg.

PRODUCT DESCRIPTION

A clear to light yellowish liquid.

PHARMACODYNAMIC PROPERTIES

Ivermectin belongs to the avermectin family, which are a macrocyclic lactone group of endectocides. 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 grated 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.

PHARMACOKINETIC PROPERTIES

Ivermectin binds extensively to plasma proteins. Due to its high lipophilic nature, Ivermectin is extensively distributed. It tends to accumulate in fat tissue, which acts as a drug reservoir and the highest levels of Ivermectin are found in liver and fat. Ivermectin is only partially metabolized. Ivermectin is mainly eliminated in the faeces as unaltered drug and faecal excretion accounts for 90% of the dose administered with <2% of the dose excreted in urine. Ivermectin is also excreted by the mammary gland.

INDICATIONS

For the treatment of infections with the following parasites:

Gastrointestinal roundworms (adult and fourth larval stage)

Haemonchus contortus, *Teladorsagia circumcincta*
Trichostrongylus spp. , *Cooperia* spp.
Strongyloides papillosus, *Chabertia ovina*
Nematodirus spp. Including *N. battus*

Lungworms(adult and fourth larval stage)

Dictyocaulus filaria

Arthropods

Nasal bot (all larval stages)
Oestrus ovis

TARGET SPECIES

Sheep.

DOSAGE AND ADMINISTRATION

The veterinary medicinal product should be given orally. The recommended dose rate is 0.2 ml product per 10 kg bodyweight (corresponding to 0.2 mg ivermectin per kg bodyweight).

DIRECTION OF USE

To ensure administration of a correct dose, body weight should be determined as accurately as possible.

CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active ingredient or any of the excipients.

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 body weigh or misadministration of the product.

Resistance to ivermectin (an avermectin) has been reported in *Teladorsagia* in sheep and goats within the EU and it is common in *Haemonchus* in sheep outside the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematode and recommendations on how to limit further selection for resistance to anthelmintics.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Fecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, and anthelmintic belonging to another pharmacological class and having different mode of action should be used. There is cross-resistance with other avermectins and with milbemycins.

SPECIAL PRECAUTION FOR USE

Special precautions for use in animals:

The timing of treatment should be based on epidemiological factors and should be customised for each individual farm. A dosing programme should be established by the veterinary surgeon. Veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control, and to reduce the likelihood of anthelmintic resistance developing. Veterinary advice should also be sought if the product does not achieve the desired clinical effect, as other diseases, nutritional disturbances or anthelmintic resistance might be involved. Avermectins may not be well tolerated in non-target species. Cases of intolerance resulting in fatalities have been reported in dogs, especially Collies, Old English Sheep Dogs and related breeds or crosses, and also in turtles/tortoises.

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

Wash hands after use. Avoid contact with skin and eyes. Do not eat, drink or smoke while handling the product. Wear impervious gloves when handling or administering the product. As absorption through skin can occur, in the event of accidental skin contact, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water.

INTERACTIONS WITH OTHER MEDICAMENTS

None known.

USE DURING PREGNANCY, LACTATION AND LAY

The veterinary medicinal product can be administered to ewes at any stage of pregnancy or lactation.

ADVERSE EFFECTS

Some sheep may cough immediately after treatment. This passing response is of no consequence.

If you notice any serious effects or other effects not mentioned in this label, please inform your veterinary surgeon.

OVERDOSE AND TREATMENT

At doses up to 4 mg ivermectin per kg administered by stomach tube (20x the recommended dose level) undesirable toxic reactions occurred. Acute symptoms (ataxia, staggering gait, incoordination, depression) were observed at the dose rate of 8 mg/kg (40x the recommended dose level) during a study carried out on 4 animals. Twenty-four hours later, the animals showed only mild incoordination and depression. Three days post dose all the animals were nearly normal. It is possible that the signs of toxaemia were due to the propylene glycol. No antidote has been identified. Symptomatic treatment may be beneficial.

WITHDRAWAL PERIODS

Meat & Offal: 10 days. Milk: Do not use in lactating sheep producing milk for human consumption. Sheep must not be treated within 60 days prior to the commencement of lactation, if milk is to be used for human consumption.

SHELF LIFE

Shelf life as packaged for sale : 2 years. Shelf life after first opening : 24 hours. Shelf life after reconstitution : 24 hours.

ALLOWABLE MAXIMUM RESIDUAL LIMIT (MRL)

Species	Food	MRLs (µg/kg)	Reference
Sheep	Fat	20 µg/kg	APPENDIX 13: ALLOWABLE MAXIMUM RESIDUAL LIMIT (MRL), *National Pharmaceutical Regulatory Division, Ministry of Health Malaysia. Third Edition, July 2014, Revised January 2020*
Sheep	Liver	15 µg/kg	

STORAGE CONDITIONS

Store in a cool place below 30ºC. Keep out of reach of children. Jauhi ubat daripada kanak-kanak.

DISPOSAL OF CONTAINERS

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

PACKAGING AVAILABLE

250ml, 500ml, 1L HDPE bottles.

MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Life Biopharma Sdn. Bhd. (company no. 546163-D)
No. 250-251, Jalan Industri Galla 13, Kawasan Perindustrian Galla, 70200 Seremban, Negeri Sembilan, Malaysia.

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