

Product Information Leaflet
LIFE LEMISOL 200mg/g WATER SOLUBLE POWDER
FOR ANIMAL USE ONLY

Name of Product :

LIFE LEMISOL 200mg/g WATER SOLUBLE POWDER

Name and Strength of Active Substance(s)

Each gram contains 235.3 mg of Levamisole Hydrochloride which is equivalent to 200 mg of Levamisole in 1 gram.

Description of Product:

A white to pale cream powder which is soluble in water. This product is to be mixed in animal drinking water and administer orally.

What is the medicine?

Levamisole is a synthetic anthelmintic belonging to the group of imidazoles. It acts on the neuromuscular system of the parasite, inhibiting acetylcholinesterase causing a sustained muscle contraction, followed by relaxation and irreversible paralysis of the parasite. It also inhibits enzyme fumarate reductase and oxidation of succinic acid in the parasite blocking the metabolism of carbohydrates. It is effective on adult and larval forms but lacks ovicidal effect. Levamisole is rapidly absorbed after oral administration. It is metabolized in the liver and is excreted rapidly, mostly by the renal route.

What is the medicine used for?

The product is for the treatment of gastrointestinal and pulmonary nematodiasis caused by nematodes sensitive to levamisole, both adult and larval forms:

Cattle and Sheep: Gastrointestinal nematodes: Trichostrongylus spp., Cooperia spp., Ostertagia spp. (except Larvae inhibited), Haemonchus spp., Nematodirus spp., Bunostomum spp., Oesophagostomum spp., Chabertia spp.; Pulmonary nematodes: Protostrongylus spp., Dictyocaulus spp.

Swine: Gastrointestinal nematodes: Ascaris suum, Strongyloides ransomi, Oesophagostomum spp.; Pulmonary nematodes: Metastrongylus spp.

Poultry: Gastrointestinal nematodes: Ascaridia columbae, Capillaria spp., Heterakis spp., Amidostomum spp.

How much and how often should you give this medicine to animal?

Dosage for cattle, sheep and pigs: 7.5 mg levamisole / kg of live weight (equivalent to 37.5 mg of medication/ kg of live weight) in a single dose.

The next dose, irrespective of the weight of the animal must not be exceeded:

- Cattle : 2,250 mg of levamisole (equivalent to 11.25 g of medication).

- Sheep: 450 mg of levamisole (equivalent to 2.25 g of medication).

In pigs from 150 kg live weight, give 350 mg of levamisole (equivalent to 1.75 g of medication) per 50 kg that exceeds that weight.

To ensure the correct dosage, the body weight should be determined as accurately as possible, and the accuracy of the dispenser should be checked.

If the animals are to be treated collectively, they should be grouped by body weight and the dosage will be made according to the weights, to avoid both underdosing and overdosing. To ensure the correct dosage administration, the weight will be determined as accurately as possible. Water consumption depends on the clinical situation of the animal and the time of year. Dilute the amount of medicine needed in water; Shake to obtain a homogeneous solution and administer to the animals.

Dosage for poultry: 20-25 mg levamisole/ kg live weight (equivalent to 100 – 125 mg of medication / kg of live weight) in a single dose.

Depending on the recommended dose, number and weight of birds to be treated and water consumption, the concentration in the drinking water should be calculated by applying the following formula:

$$\text{gram of medicine / litre of drinking water} = \frac{\text{dose of active substance (mg/kg bodyweight/day)} \times \text{mean weight of animal (kg)}}{\text{mg of substance active in g of medication (mg/g)} \times \text{average consumption of water (litres/day)}}$$

In all cases, the schedule or timing of treatment should be based on epidemiological factors and be customized for each farm. The treatment program must be established by the veterinarian.

What should you do if you miss a dose for the animal?

Give the dose as soon as possible unless it is time for next dose to be given. Do not double up the dose unless it is directed by the veterinarian. Consult veterinarian.

When should you not give this medicine to animal?

Do not use in case of known hypersensitivity to the active substance and/or to any excipient.

Warnings: The following practices should be avoided since they increase the risk of developing resistances and that in the latter case, the therapy is ineffective:

- Frequent and repeated use of anthelmintics of the same class or during an extended period of time.
- Underdosing may be due to incorrect estimation of body weight, misuse of the medication or lack of calibration of the metering device.

For clinical cases in which resistance to a certain anthelmintic is suspected, this fact should be investigated through appropriate trials (eg, egg count reduction test in feces). If the results indicate clearly resistance to a particular anthelmintic, then anthelmintic from another pharmacological group or with a different mechanism of action should be given.

Care that should be taken when giving this medicine to animal:

Special precautions for use in animals: None.

Specific precautions to be taken by the person administering the veterinary medicinal product to animals: People with known hypersensitivity to levamisole should avoid all contact with the veterinary medicinal product. Handle medication carefully to avoid inhaling dust, as well as contact with the skin and eyes. Take specific precautions during its incorporation into the water: Take appropriate measures to prevent the spread of dust during the incorporation of the drug into drinking water. Use an anti-dust mask, gloves, protective garment and approved safety glasses. If exposure of the skin or eyes occurs accidentally, wash immediately with plenty of water. Do not smoke, eat or drink while handling the medicine.

What other medicine or food should be avoided while giving this medicine to animal?

Do not administer organophosphorus compounds from 14 days before until 14 days after administration of levamisole.

Statement on usage during pregnancy and lactation

Studies in laboratory animals have not shown teratogenic, fetal toxic or toxic effects on the mother. Do not use this medicine in the last third trimester of gestation. Do not use on birds during laying or within the four weeks prior to the start of laying period.

Undesirable effects/side Effects

Abdominal pain, salivation, cough, nausea and vomiting may be observed.

What to do when you have given more than the recommended dosage to the animal?

Immediately stop the medication and consult the veterinarian. Symptoms of overdose poisoning are similar to those of organophosphate poisoning: hyperexcitability, salivation, and mild muscle tremors.

When should you consult your veterinarian?

When you observe side effect(s), overdose or miss doses.

Withdrawal Period(s)

Meat: Cattle, sheep and pigs: 14 days ; Poultry: 7 days ; Milk: Not authorized for use in lactating animals whose milk is used for human consumption. Eggs: Not authorized for use in laying birds whose eggs are used for human consumption. Do not use within 4 weeks prior to start of laying.

Shelf-life

Shelf life as packaged for sale: 3 year. Shelf life after first opening : 24 hours. Shelf life after reconstitution : 24 hours

Allowable Maximum Residual Limit (MRL)

Cattle, pig, sheep and poultry: Muscle, kidney, fat = 10 µg/kg ; Liver = 100 µg/kg. [Ref. Codex Alimentarius Commission MRL, July 2015][REGOVP, Version 3-July 2014][In accordance to Fifteenth A Schedule, [Regulation 40], Food Act 1985].

How should you keep this medicine?

Store in a dry place below 30°C. Keep out of reach of children. Jauhi ubat daripada kanak-kanak.

Disposal of Containers

Emptied aluminum sachet must be disposed according to local government regulations.

Dosage Forms and packaging available

Available in 200g, 500g and 1000g powder per sachet

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.

Date of Revision

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