

For Veterinary Use Only.


Actipar[®]

Solution for Injection

Veterinary Systemic Anthelmintic

COMPOSITION:

A colorless and clear solution for injection containing 100mg levamisole MCl per each ml.

PHARMACOLOGICAL PROPERTIES:

Actipar Solution for Injection is a wide spectrum anthelmintic preparation intended for the treatment of enterobius vermicularis in stomach-intestine and lung in ruminants containing levamisole, a derivative of imidazothiazole.

Actipar Solution for Injection; the antinematodal activity of levamisole in its composition which is a member of imidazothiazole group is based on blocking the nerve system by consistently stimulating the autonomic parasitic ganglions. Also, as in benzimidazoles, it inhibits the activity of fumarate reductase and deteriorates the carbohydrate metabolism of the parasite. Ostertagia and Haemonchus species may develop resistance to levamisole which are within the effect spectrum. Half life is 9.3 hours in oral administration and 6.9 hours in intramuscular administration. In cattle, 83-84% of the drug is excreted through the urine whereas 9-14% is through stools.

AREA OF USE / INDICATIONS:

Actipar Solution for Injection in sheep and cattle;

Stomach-intestine enterobius vermicularis: Haemonchus sp., Oestertagia sp., Trichostrongylus sp., Nematodirus sp., Cooperia sp., Bunostomum sp., Chabertia ovina and Oesophagostomum sp.

Pulmonary Pinworms: Dictyocaulus sp.

Eye parasites: Effective for Thelazia sp. species.

USAGE AND DOSAGE:

It is administered subcutaneously and intramuscularly. Unless recommended otherwise by veterinary surgeon, general dose is 5-7.5mg for 1 kg live weight. 1-1.5ml is administered for 20kg live weight. It should not be combined with other drug during administration and administered more than 10 ml instead of single use.

SPECIFIC CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES:

Use during pregnancy: Safe in pregnant women at the recommended doses.

UNDESIRE/SIDE EFFECTS

Temporary puffiness may be observed in the application area after the injection.

DRUG INTERACTIONS:

- It should not be used concurrently with the piperazine salts due to antagonistic activity.
- Concurrent use with tetrahydroprimidines (pirantel and morantel salts) may result in the increment of toxicity.
- It should not be used together with organophosphorous insecticide compounds before and after 14 days in the treatments with levamisole.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE:

In the case of overdose, symptoms of intoxication begins in a short time as 5-15 minutes following the administration and reaches peak value in the 30th minute. High doses lead to nausea, vomiting, muscle tremors, agitations, respiratory distress, slowing down in heart rates, hypotension, urination, lying down, respiratory insufficiency and mortality. Liquid therapy and symptomatic treatment are applied during the treatment. As in the case of organophosphorous insecticide intoxication, intravenous atropine sulphate treatment is recommended in levamisole intoxication.

WARNINGS ON DRUG RESIDUES IN FOOD:

Withholding Period (WHP); is 28 days for meat in cattle and sheep as of the final drug administration. It is not administered to cattle and sheep from which milk is produced for human consumption.

CONTRAINDICATIONS:

- It should not be administered to animals known to be sensitive to levamisole.
- It should not be administered to animals with liver and kidney failure.
- Concurrently administration with organophosphorous compounds is contraindicated depending on levamisole. Therefore, organophosphorous compounds should not be used 14 days before and after drug administration.

GENERAL WARNINGS:

Consult your veterinary surgeon before using or in case an undesired effect is observed. Keep out of reach of children. Keep away from food products.

PRECAUTIONS TO BE TAKEN BY THE USER AND WARNINGS FOR VETERINARY SURGEONS:

Use clean and sterile injector during administration. Levamisole may cause skin allergic reactions in hypersensitive humans. It is recommended to use gloves and mask during administration. Avoid contact with hands and eyes.

STORAGE CONDITIONS AND SHELF LIFE:

Store in room temperature (15 - 25°C) away from light. Shelf life is 4 years as of the production date.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES:

- Due to the sensitivity of the race and herd, intoxications and mortality may be seen in goat even at normal doses.
- It is highly hazardous for horses. It may lead to mortality at the dose of 20mg/kg depending on levamisole. It is toxic for cats and dogs in the manner that it may cause mortality.

COMMERCIAL PRESENTATION FORM INDICATING THE QUALITY AND QUANTITY OF THE PACKAGE:

Presented to the market in 20, 50 and 100ml brown vials in cardboard boxes.

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon's prescription in pharmacies and veterinary surgeries (VSP).

APPROVAL DATE OF PACKAGE INSERT: 14.11.2006

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS AUTHORIZATION DATE AND NO : 15.07.2004-13/078

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

Alke Saęlık Ürünleri San. ve Tic. A.Ş

Dolayoba, Çınardere Mh. 3. Petek Sk. No: 18, 34896 Pendik-İSTANBUL

NAME AND ADDRESS OF MANUFACTURER COMPANY:

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