

For Veterinary Use Only

Ricoben[®]

Solution for Injection

Veterinary Anthelmintic

COMPOSITION:

RICOBEN Solution for Injection is a straw and sterilized solution containing 100 mg Ricobendazole in each ml.

PHARMACOLOGICAL PROPERTIES:

Ricobendazole (albendazole sulfoxide) in RICOBEN Solution for Injection composition is a broad spectrum anthelmintic derivative benzimidazolecarbamate. Helminths sensitive to ricobendazole bonds to tubulin in skin and intestinal cells, and inhibits the polymerization of this substance as microtubules. Microtubule loss declines glucose intake and ATP production, and consumes glycogen reserves. Parasite without energy is removed by being immobilized. Its absorption is way faster after oral administration when comparing with other molecules in benzimidazole group. It has been reported ricobendazole metabolites to be determined as 47% in urine samples 9 days after the administration. In sheep the systemic bioavailability of ricobendazole is higher in subcutaneous (subcut) administration (96%) than intraruminal (IR) administration (27%). C_{max} acquired as a result of subcut administration (2.09 ±0.24 mcg/ml) is higher than the acquired by IR administration (0.44±0.10 mcg/ml), and its T_{max} time is shorter in subcut administration (3.81 ±0.45 h) than IR administration (7.31 ±.65 h). C_{max} acquired as a result of subcut administration (1.9 ±0.41 mcg/ml) is higher than the acquired by IR administration (1.7±0.54 mcg/ml), and its T_{max} time is shorter in subcut administration (9.3 ±2.12 h) than IR administration 11.6±1.05 h), in cattle. Elimination half-life is around 8-12 hours.

Ricobendazole at lower doses than the efficient dose in adult parasites is efficient against also indicated parasites' eggs. RICOBEN Solution for Injection affects eggs ovicidal by corrupting anaerobic energy metabolisms of female parasites. Most of ricobendazole is excreted through defecation.

AREA OF USE / INDICATIONS:

RICOBEN Solution for Injection is indicated in treatment and control for clinical and subclinical gastroenteritis caused by stomach and intestinal pinworm included in spectrum effect, parasitic bronchitis caused by pulmonary nematodes, taenia infections, chronic fascioliasis in cattle and sheeps. RICOBEN Solution for Injection spectrum effect includes parasites below.

Stomach-Intestinal pinworms (Gastrointestinal nematodes, young and adults): Ostertagia sp (benzimidazole resistant inhibited larvae including L4), Haemonchus sp., Trichostrongylus sp., Cooperia sp., Capillaria sp., Chabertia sp., Nematodirus sp., Bunostomum phlebotomum., Strongyloides papillosus., Oesophagostomum radiatum

Lung pinworms (Lung nematodes, young, L4, and adults): Dictyocaulus viviparus

Liver fluke: Fasciola hepatica and Fasciola gigantica (adult stages)

Taenias: Moniezia sp.

USAGE AND DOSAGE

Unless recommended otherwise by a Veterinary Surgeon RICOBEN Solution for Injection is administered subcutaneously in cattle and sheep. Pharmacological dose of ricobendazole in cattle and sheep is 3.75 mg / kg live weight (1.5 ml/40 kg live weight) in stomach-intestine and lung pinworms, 5 mg/kg live weight (2 ml/40 kg live

weight) in taenias, 7.5 mg/kg live weight (3 ml/40 kg live weight) in liver flukes and inhibited larvae of *Ostertagia ostertagi*.

Practice Dose Scale:

Animal Species	Live Weight	Stomach-intestine enterobius vermicularis: (3,75 mg / kg live weight)	Taenias (5 mg/kg live weight)	Liver fluke And <i>O. ostertagi</i> inhibited larvae (7.5 mg/kg live weight)
Sheep	20 kg	0.75 ml	1 ml	1.5 ml
	40 kg	1.5 ml	2 ml	3 ml
	60 kg	2.25 ml	3 ml	4.5 ml
Cattle	80 kg	3 ml	4 ml	6 ml
	160 kg	6 ml	8 ml	12 ml
	240 kg	9 ml	12 ml	18 ml
	320 kg	12 ml	16 ml	24 ml
	480 kg	18 ml	24 ml	36 ml

In animals requiring volumes higher than 10 ml it is recommended the volume to be divided and administered to separate areas.

SPECIFIC CLINICAL PARTICULARS AND SPECIAL WARNINGS FOR TARGET SPECIES

- As preservative it is recommended to be administered at least twice yearly one of them in spring and the other in fall.
- In order to prevent grazing lands to be infected by parasites it is recommended an administration to be executed before going to the grazing land, and animals treated to be kept closed for 8-12 hours in terms of completing ovicidal effect, and preventing grazing land infectivity.
- Disinfection is recommended to be carried out two weeks before releasing the rams.
- When determining the dose live weight of animals is to be evaluated carefully.
- Administrations with cachectic animals, and animals under a lot of stress should be observed carefully.

Use during pregnancy: Teratogenicity and embryotoxic effect of benzimidazole derivatives in first 1/3 period of pregnancy should be considered.

UNDESIRE/SIDE EFFECTS

No known side effect at recommended doses in cattle and sheep.

DRUG INTERACTIONS

There is no incompatibility of ricobendazole with other medicines.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

In case of poisoning symptomatic intervention should be executed as per clinical symptoms.

WARNINGS ON DRUG RESIDUES IN FOOD

Withholding Period (WHP): Meat type cattle should not be sent to slaughtering during treatment and before 14 days after the last drug administration, and sheep before 10 days after the last drug administration, cow and sheep milk obtained within 3 days (6 milking) should not be offered for human consumption.

CONTRAINDICATIONS

Avoid administrating in animals with hypersensitivity against ricobendazole. It should not be administered in animals with liver and kidney failure.

GENERAL WARNINGS

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

STORAGE CONDITIONS AND SHELF LIFE

Store in its package at room temperature (15 -30°C). Keep away from direct sunlight. Shelf life is 2 years as of the production date.

DISPOSAL AFTER USE AND WARNINGS FOR NON-TARGET SPECIES:

It should not be used in goats, horses and other equidae.

COMMERCIAL PRESENTATION FORM

Offered for sale as 20, 50, and 100 ml in cardboard box packages, and as 250 ml amber vials in plastic cans.

PLACE AND CONDITIONS OF SALE

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

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