**For Veterinary Use Only**

# PASTHEPAN®

**Oral Gel**

**Veterinary Oral Antiparasitary**

## COMPOSITION

Pasthepan Oral Gel is an adhesive, fluid gel containing 200mg triclabendazole and 150mg levamisole per each 0.9g dose.

## PHARMACOLOGICAL PROPERTIES

Pasthepan Oral Gel is a broad-spectrum anthelmintic obtained with the combination of triclabendazole which is a thio-benzimidazole and levimasole which is a derivative of imidathiazol intended to be used for the treatment of adult and young larval forms of liver trematodes; gastro-intestinal parasites and pulmonary pinworms in sheep and cattle.

Triclabendazole contained in Pasthepan Oral Gel is a benzimidazole carbamate fasciolicide which is effective for all larval and adults forms of one day Fasciola hepatica and Fasciola gigantica, which are among liver trematodes. Unlike other benzimidazoles, Triclabendazole, multiply inhibits the energy metabolism of Fasciola trematodes and creates a specific lethal effect. The special paste formulation of Pasthepan Oral gel is rapidly diffused in the digestive system due to the catalyser carriers functioning in the absorption of active substances, and activates the anti-parasitic action. When administered orally to sheep, triclabendazole contained within the composition of Pasthepan, is absorbed rapidly through digestive tract and reaches maximum blood concentration within 18 hours. It binds to plasma proteins with a ratio of more than 90% and reaches high concentrations in particularly liver tissue. More than 80% of it is eliminated as metabolites, whereas 70% of it through stools within 7 days.

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. Levamisole contained within the composition of Pasthepan Oral Gel is rapidly diffused in the rumen when administered orally, and reaches maximum blood concentration within 2-4 hours. The half life is 9.3 hours when administered orally. 68-78% of it is eliminated through urine, whereas 17-33% is via stools within 72 hours.

## AREA OF USE/INDICATIONS

Pasthepan Oral Gel is used in the treatment of cattle and sheep for the following;

Abomasum nematodes

Haemonchus spp. (Adult, L4 and immature forms)

Ostertagia spp. (Adult, L4 and immature forms)

Small intestinal nematodes

Cooperia spp. (Adult and larval forms)

Trichostrongylus spp. (Adult and larval forms)

Bunostomum spp. (Adult and larval forms)

Large intestinal nematodes;

Oesophogustomum spp. (Adult and larval forms)

Pulmonary Pinworms;

Dictyocaulus spp (Adult and larval forms)

Liver trematodes

Fasciola hepatica and Fasciola gigantica (adult and all larval forms).

**USAGE AND DOSAGE**

Pasthepan Oral Gel is sprayed into the mouth of cattle and sheep with the special dosage indicator package ensuring that 0.9g is the standard dose for 20kg live weight. In general administration, triclabendazole corresponds to 10mg/kg whereas levamizole corresponds to 7.5mg/kg live weight. In the cases of acute fasciolasis developed by the immature forms, 1 dose should correspond to 15kg live weight as per the recommendation of veterinary surgeon.

| Animal Species | Live Weight | Administration Dose Acute-subacute Fasciolasis | Live Weight | Chronic fasciolasis |
|---|---|---|---|---|
| Lamb Sheep | Up to 15 kg | 1 dose | Up to 20 kg | 1 dose |
| | 16 – 30 kg | 2 doses | 21 – 40 kg | 2 doses |
| | 31 - 45 kg | 3 doses | 41–60kg | 3 doses |
| | 46–60kg | 4 doses | 61–80kg | 4 doses |
| Calf Steer Cattle | Up to 60kg | 4 doses | Up to 80 kg | 4 doses |
| | 61 – 75 kg | 5 doses | 81 - 100 kg | 5 doses |
| | 76 – 90 kg | 6 doses | 101 – 120 kg | 6 doses |
| | 91 – 105 kg | 7 doses | 121–140kg | 7 doses |
| | 106 – 115 kg | 8 doses | 141 - 160 | 8 doses |
| | 116 – 130 kg | 9 doses | 161–180kg | 9 doses |
| | 131 – 145 kg | 10 doses | 181 – 200 kg | 10 doses |
| In bigger cattle, 1 dose per each 15kg should be administered in acute cases and 1 dose should be administered per each 20kg in chronic cases by taking into consideration the body weight. | | | | |

**SPECIFIC CLINICAL PARTICULARS AND SPECIAL WARNINGS FOR TARGET SPECIES**

By taking into consideration the biological periods of parasites, it recommended to perform two administrations when the animals are taken to pasture feeding in spring and after they come back from the pasture in autumn in open animal holdings.

In closed holdings, the administrations should be performed by keeping in mind that the temperature increases in spring and decreases in autumn. Avoid repeat dose administration to animals more than 3 weeks.

The live weight of the animal should be evaluated with special care while specifying the dose.

Administrations to cachectic animals and the ones under heavy stress should be monitored with attention.

**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.

Avoid using with organophosphorus compounds (trichlorphone, dichlorvos, etc.), phenicols and diethylcarbamazine due to nicotinic effects.

**SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE**

Overdoses may result in acute levamisole intoxication. In case intoxication signs are observed such as nausea, vomiting, muscle tremors, convulsions, respiratory distress, deceleration of heart rates, hypotension, urination, prostration and respiratory insufficiency; symptomatic treatment should be applied.

**WARNINGS ON DRUG RESIDUES IN FOOD**

Withholding Period (WHP): Meat type cattle and sheep should not be sent for slaughtering during treatment and before 28 days following the final drug administration.

It is not administered in dairy cattle and sheep from which milk is produced for human consumption.

**CONTRAINDICATIONS**

Avoid using in sensitive animals with sensitization to levamisole or triclabendazole.

It should not be administered to animals with renal failure.

Avoid using with cholinomimetic drugs such as tetrahydropyrimidines, diethyl carbamazine and organophosphorus insecticides due to nicotine like effect of levamisole.

Use during pregnancy: Despite triclabendazole and levamisole are safe at recommended doses in terms of pregnancy, the teratogenicity risk of benzimidazole derivatives should be taken into consideration within the 1/3rd period of pregnancy.

**GENERAL WARNINGS**

Consult your Veterinary Surgeon before using and in case an undesired effect is observed. Check over the application technique of the dispenser package before use. Keep out of reach of children.

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

Avoid eating, drinking and smoking while applying the drug. Avoid contact with skin and eyes. In case of contact, wash your skin, hands and eyes with plenty of water. Sensitivity reactions (idiosyncratic) may be seen in a limited number of people who have applied the drug. Wash your hands following drug administration.

**STORAGE CONDITIONS AND SHELF LIFE**

Store at room temperature protected from sunlight.

Shelf life is 3 years as of the production date.

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

Presented to the market in 1, 2 and 4 tube packages of 45g (50 doses) and 315g (350 doses) placed in polystyrene boxes.

**PLACE AND CONDITIONS OF SALE**

Sold with Veterinary Surgeon’s prescription in pharmacies, private animal hospitals and veterinary surgeries.

**APPROVAL DATE OF PACKAGE INSERT:** 04.03.2005

**MINISTRY OF AGRICULTURE AND RURAL AFFAIRS MARKETING AUTHORIZATION DATE - NO**

12.06.2002 -11/1057

**NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:**

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