For Veterinary Use Only

PASTHELMIN®

Oral Gel

Veterinary Antihelmintic

COMPOSITION

Pasthelmin Oral Gel is cream to yellowish coloured, adhesive, fluent gel containing 100mg oxfendazole and 275mg oxyclozanide per each 0.9g dose.

PHARMACOLOGICAL PROPERTIES

Pasthelmin Oral Gel, a broad spectrum applicative gel obtained with the combination of oxfendazole from benzimidazole carbamate group and a derivative of salycilanide, oxyclozanide, has been developed to be applied for the treatment of gastro-intestinal parasites, pulmonary pinworms and liver trematodes in cattle, sheep, calf and lamb.

Oxfendazole contained in the composition of Pasthelmin Oral gel is a benzimidazole carbamate with antinematodal activity. They inhibit fumarate reductase activity in parasites and block glucose absorption while enhancing glycogen use and reducing ATP (adenosine triphosphate) production. Therefore, parasite deteriorates the mechanism of energy. When administered orally to ruminants it is rapidly diffused in rumen and Oxfendazole is partially transformed into fenbendazole in rumen and thus absorbed. Oxfendazole and its metabolite reach peak plasma level within approximately 12-18 hours. Its concentration is high in the liver, kidneys and intestines. The half life is 18.7 hours. After 48 hours, it is excreted from the body mainly through bile in the form of glucoronide compound.

A derivative of salycilanide, oxyclozanide, inhibits fumarate reductase enzyme as well as deteriorating phosphorolase binding of energy metabolism. The special paste formulation of **Pasthelmin 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. Oxyclozanide reaches peak plasma concentration within 45 minutes following administration. The half life is (t 1/2γ) 6.4 days. Oxyclozanide is mainly eliminated through stools and, at lower amounts (1.2 – 1.9%), through urine.

T.colubriformis, Ostertagia sp. ve Haemonchus species may develop resistant strains against benzimidazole group antihelmintics.

AREA OF USE/INDICATIONS

Pasthelmin Oral Gel is used for the treatment and protection of parasitic infestations in cattle and sheep caused by the following;

Pulmonary Pinworms: *Dictyocaulus viviparus, Dictyocaulus filaria*

Gastro-intestinal parasites: *Haemonchus concortus, Haemonchus placei*, adults, *Ostertagia ostertagi*, including Adult, L-4 and inhibited forms, *Nematodirus sp.;* Adult, L-4, *Trichostrongylus axei*; adult; *Bunostomum phlebutomum*; adult, *Cooperia sp.* adult and L-4; *Monezia sp*., adult; *Oesophagostomum radiatum*; adult, Chabertia sp. adult, Oesophogustomum sp.; adult, Trichuris sp; adult.

Liver parasites: *Fasciola hepatica*, *Fasciola gigantica*

USAGE AND DOSAGE

Pasthelmin Oral Gel is administered to oral cavity in cattle and sheep at a dose of 0.9g per 15-20kg live weight by its special dose indicator package. In this administration oxfendazole corresponds to 5mg – 6.5mg/kg live weight, while oxyclozanide corresponds to 13.5mg – 15mg/kg live weight.

Table of Practical Dose

Animal Species	Live Weight	Administration Dose
Lamb Sheep	15–20kg	1 dose
	21-40 kg	2 doses
	41–60kg	3 doses
	61–80kg	4 doses
Calf Steer Cattle	Up to 60kg	3 doses
	61–80kg	4 doses
	81-100 kg	5 doses
	101-120 kg	6 doses
	121–140kg	7 doses
	141-160 kg	8 doses
	161–180kg	9 doses
	181–200kg	10 doses
	201–220kg	11 doses
	221 - 240 kg	12 doses
	250 - 500	13 – 20 doses

SPECIFIC CLINICAL PARTICULARS AND SPECIAL WARNINGS FOR TARGET SPECIES

- By taking into consideration the biological periods of parasites, it recommended to perform at least 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.
- With respect to the timing of parasitic fight, the parasite incidence of the area, climate, environmental conditions and the conditions of the animals should be taken into consideration in order to detect the accurate timing.
- In closed holdings, the administrations should be performed by keeping in mind that the temperature increases in spring and decreases in autumn.

UNDESIRED EFFECTS

Temporary effects may be observed including rarely diarrhoea and frequent excretion.

DRUG INTERACTIONS

Avoid using with bromsalan compounds (such as hilomid which is a mixture of equial amounts of dibromsalan and tribromsalan). In case of concurrent administration, it may cause abortions in cattle and mortality in sheep.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE

When administered to sheep at a dose of 60mg/kg or higher doses, mortality may occur. In case of administration to cattle at a dose of 30mg/kg certain indications of intoxication may be observed.

Dose adjustment should be performed accurately for the animals with weak condition and parasite invasion. When given at a dose much higher than the therapeutic dose anorexia, depression, ataxia, tachypnea, incoordination of movements, saliva increase and spasm may be seen depending on the amount administered. Intervention is performed in accordance with the symptoms.

WARNINGS ON DRUG RESIDUES IN FOOD

Withholding Period (WHP); Meat type cattle and sheep should not be sent for slaughter during the treatment and before 28 days and 21 days, respectively, following final administration. Milk produced from cattle should not be offered for human consumption during the treatment and for 5 days (10 milkings) following the final administration.

It shall not be administered in dairy sheep from which milk is produced for human consumption.

CONTRAINDICATIONS

Avoid administrating to animals with liver failure as it has a low treatment safety.

Use during pregnancy: Due to the fact that oxfendazole has a potential of teratogenic effect as the other benzimidazoles, it should not be administered to animals which are in the first 1/3rd semester of pregnancy and also 1 month before the delivery.

GENERAL WARNINGS

Consult your Veterinary Surgeon before using and in case an undesired effect is observed. Keep out of reach of children.

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

Administer Pasthelmin Oral Gel in cattle at maximum 20 doses. Read the application technique on the package before use. Wash your hands with plenty of water after contact with the product.

STORAGE CONDITIONS AND SHELF LIFE

Store at room temperature protected from sunlight.

Shelf life is 4 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 (VSP).

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS MARKETING AUTHORIZATION DATE - NO : 05.06.2002 / 11-1055

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

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