



VERMIXEL CAT PALATABLE TABLETS

Description and Composition

VERMIXEL CAT PALATABLE TABLETS is a yellow tablet, with score. Each tablet contains 230mg Pyrantel Embonate and 20mg Praziquantel as its active ingredients.

Pharmacodynamics

The product is an anthelmintic containing praziquantel, a pyrazinoisoquinoline derivative, and pyrantel, a tetrahydropyrimidine derivative (as embonate), which is active against nematodes and cestodes.

Praziquantel acts on cestodes; its spectrum of action includes *Taenia taeniaeformis*. It acts on all stages of development of these intestinal parasites in cats. Parasites absorb praziquantel very quickly through their surface. Praziquantel distributes homogeneously in the parasite. *In vitro* and *in vivo*, very quickly significant lesions are observed in the parasitic integument, leading to contraction and paralysis of the parasites. This rapid onset effect is explained in particular by the fact that praziquantel modifies the permeability of the parasite membrane to calcium ions; which causes a deregulation of parasitic metabolism.

No resistance to praziquantel has been reported in cats. The mechanism of resistance has been studied in mice. In the parasites least susceptible to praziquantel, there was a lower inhibition of liver enzymes, and therefore a greater metabolism of praziquantel, inducing a lower exposure for the parasite.

Pyrantel acts specifically on nematodes, in particular *Toxocara cati*, *Ancylostoma tubaeforme* and *Ancylostoma braziliense*. It exerts a nicotinic-like cholinergic agonist effect and causes spastic paralysis of the nematodes through depolarizing neuromuscular blockade.

No resistance to pyrantel has been reported in cats. The mechanisms of resistance are not clearly identified but seem to involve the different subtypes of cholinergic receptors, to which pyrantel binds, in the parasite.

Pharmacokinetics

Praziquantel is very rapidly and almost completely absorbed in the stomach and small intestine after oral administration. Peak plasma concentrations are usually reached within 0.3 to 2 hours. Praziquantel is distributed very quickly to all organs. The half-life times of praziquantel C¹⁴ and its metabolites range from 2 to 3 hours. Praziquantel is rapidly metabolized in the liver. Of all the metabolites, the main one is 4-hydroxycyclohexyl derived from praziquantel. Praziquantel is completely eliminated within 48 hours in the form of metabolites, between 40 and 71% in the urine and, via bile, between 13 and 30% in the faeces.

Pyrantel in the form of embonate is very poorly absorbed from the gastrointestinal tract.

Indication

Treatment of mixed infestations in cats, caused by:

- Adult nematodes: *Toxocara cati*, *Ancylostoma tubaeforme* and *Ancylostoma braziliense*.

- Cestodes: *Taenia taeniaeformis*.

Recommended Dose

Oral.

5mg praziquantel and 20mg pyrantel (equivalent to 57.5mg as pyrantel embonate) per kg body weight, or 1 tablet per 4kg body weight in a single dose.

In order to ensure proper dosage, body weight should be determined as accurately as possible.

The dosage is presented in the following table:

Animal weight (kg)	Number of tablets per dose
1.0 – 2.0 kg	½
2.1 – 4.0 kg	1
4.1 – 6.0 kg	1 + ½
6.1 – 8.0 kg	2

The tablets can be given directly into the mouth or mixed with food.

No dietary measures are necessary.

In the event of an infestation by *Toxocara cati*, especially in kittens, complete elimination cannot be considered and the risk of transmission to humans may persist. Additional treatments should be carried out at intervals of 14 days until 2 to 3 weeks after withdrawal, using a product effective against *Toxocara cati*.

Route of Administration

To be given by oral administration in cats.

Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

Do not use concomitantly with cholinergic compounds (e.g., piperazine).

Do not use in cats younger than 8 weeks of age or weighing less than 1 kg.

Refer section 'Interactions with Other Medicaments' and 'Pregnancy and Lactation'.

Warning and Precautions

Special warnings for each target species

Taenia taeniaeformis infestation will certainly recur unless control of intermediate hosts such as rodents is undertaken.

Because they increase the risk of developing resistance and can eventually lead to ineffective treatment, the following practices should be avoided:

- Too frequent and repeated use of anthelmintics of the same class over a prolonged period of time.
- Under-dosing due to underestimation of the animal's weight or poor administration of the product.

Unnecessary use of antiparasitic drugs or use outside of the recommendations may increase selection pressure and reduce drug activity.

The decision to use the product shall be based on confirmation of the identification of the parasitic species and the parasite load or risk of infection on the basis of the epidemiological characteristics of that parasite for each animal. The possibility that other animals in the household may be a source of reinfestation by the target pests should be taken into consideration and these should be treated, if necessary, with an appropriate product. The use of the product should take into account local information on the susceptibility of target pests, where available.

Tapeworm infestation occurs in cats at the earliest during the third week of life.

Special precautions for use

Special precautions for use in animals

The tablets are flavoured. To prevent accidental ingestion, keep the tablets out of the reach of pets.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after using the product.

In case of accidental ingestion, seek immediate advice from a doctor and show the package leaflet or label.

Discard any unused portion of the tablet.

Interactions with Other Medicaments

Do not use concomitantly with other cholinergic compounds (e.g., piperazine) because the specific activities of these cholinergic compounds (neuromuscular paralysis of parasites) may inhibit the efficacy of pyrantel (spastic paralysis of parasites).

Pregnancy and Lactation

The safety of the veterinary medicinal product has not been established in gestation or lactation.

Gestation:

Not recommended for use during gestation.

Laboratory studies in rats and mice for pyrantel and praziquantel did not demonstrate teratogenic, fetotoxic, or embryotoxic effects.

Laboratory studies in cats for praziquantel did not show any teratogenic, fetotoxic, or embryotoxic effects.

Lactation:

Can be used during lactation.

Fertility:

Praziquantel and pyrantel did not show any effect on reproductive parameters in cats.

Side Effects

Cats:

Very common (>1 animal / 10 animals treated):	Diarrhoea ^{1,2}
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive disorders (for example: hypersalivation, vomiting) ³ Neurological disorder (eg. ataxia) ³

¹ related to pest removal

² transient

³ benign and transient

It is important to report adverse reactions. Notification allows for continuous monitoring of the safety of a veterinary drug.

Symptoms and Treatment of Overdose

At three times the recommended dose of the praziquantel/pyrantel combination, vomiting and diarrhoea were observed.

Storage Condition

Store below 30°C. Protect from light.

Shelf life

3 years.

Packing

30, 60, 100, 120, 200, 500 tablets

Manufacturer & Product Registration Holder

Range Pharma Sdn Bhd

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