

CESTEM & CESTEM XL Flavoured tablets for dogs

Presentation

Cestem flavoured tablet is a yellow brown divisible tablet containing 150mg febantel, 50mg pyrantel and 50mg praziquantel with a liver flavouring.

Cestem XL flavoured tablet is a yellow brown divisible tablet containing 525mg febantel, 175mg pyrantel and 175mg praziquantel with a liver flavouring.

Uses

For the control of the following gastrointestinal tapeworms and roundworms in adult dogs and puppies.

Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).

Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).

Whipworms: *Trichuris vulpis* (adults).

Tapeworms: *Echinococcus* spp., *Taenia* spp., *Dipylidium caninum* (adult and immature forms).

Dosage and administration

The recommended dose rates are: 15 mg/kg bodyweight febantel, 5 mg/kg pyrantel (as embonate) and 5 mg/kg praziquantel. This is equivalent to 1 tablet of Cestem per 10 kg bodyweight or 1 tablet Cestem XL per 18-35kg, in one administration.

Dosages are as follows:

Cestem	
Body weight (kg)	Cestem Tablet quantity
3-5	½
6-10	1
11-15	1 ½
16-20	2
Cestem XL	
Body weight (kg)	Cestem XL Tablet quantity
17.5	½
18 – 35	1
36 – 52.5	1 ½
53 – 70	2

The smaller tablet size, Cestem, should be used to achieve accurate dosing in dogs weighing less than 17.5 kg.

For oral administration, the tablets can be given to the dog with or without food. No starvation is needed before or after treatment.

Puppies should be treated at 2 weeks of age and every 2 weeks until 12 weeks of age. Thereafter they should be treated at 3 month intervals. It is advisable to treat the bitch at the same time as the puppies.

For the control of *Toxocara canis*, nursing bitches should be dosed 2 weeks after giving birth and every two weeks until weaning.

For routine worm control adult dogs should be treated every 3 months.

For routine treatment a single dose is recommended.
In the event of heavy roundworm infestation a repeat dose should be given after 14 days.

Contra-indications, warnings, etc.

As a precautionary measure to prevent the establishment of *Echinococcus multilocularis* in the UK, it is recommended that all dogs entering the country be treated with praziquantel.

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*. Tapeworm infestation may reoccur unless control of intermediate hosts such as fleas, mice etc is undertaken.

The product is not recommended for use in puppies of less than 3 kg bodyweight.

Use during pregnancy and lactation

Treatment during the first 4 weeks of pregnancy should be avoided.

The product may be used during lactation (see Section 4.9 below).

Interaction

Do not use simultaneously with piperazine.

Plasma concentrations of praziquantel may be decreased by concomitant administration with drugs that increase the activity of cytochrome P-450 enzymes (e.g. dexamethasone, phenobarbital).

Overdose

The veterinary medicinal product is well tolerated in dogs. In safety studies doses of 5 x or greater gave rise to occasional vomiting.

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

Wash hands after administration to the animal.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to any of the ingredients should avoid contact with the veterinary medicinal product.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Pharmaceutical precautions

This veterinary medicinal product does not require any special storage conditions.

Return any halved tablet to the opened blister pack and use within 7 days.

KEEP OUT OF REACH OF CHILDREN.

For animal treatment only.

Legal category

NFA-VPS

Package quantities

Box containing 1 blister of 2 tablets

Box containing 2 blisters of 2 tablets

Box containing 1 blister of 8 tablets

Box containing 13 blisters of 8 tablets

Box containing 52 blisters of 2 tablets

Not all pack sizes may be marketed.

Further information

PHARMACOLOGICAL PROPERTIES

ATCvet code: QP52AA51.

Pharmacotherapeutic group: anthelmintics.

Pharmacodynamic properties

In this fixed combination pyrantel and febantel act against all relevant nematodes (ascarids, hookworms, and whipworms) in dogs. In particular the activity spectrum covers *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum* and *Trichuris vulpis*. This combination shows synergistic activity in the case of hookworms and febantel is effective against *T. vulpis*.

The spectrum of activity of praziquantel covers all important cestode species in dogs, in particular *Taenia* spp, *Dipylidium caninum*, *Echinococcus granulosus* and *Echinococcus multilocularis*. Praziquantel acts against all adult and immature forms of these parasites.

Praziquantel is very rapidly absorbed through the parasite's surface and distributed throughout the parasite. Both *in vitro* and *in vivo* studies have shown that praziquantel causes severe damage to the parasite integument, resulting in the contraction and paralysis of the parasites. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolisation of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, especially calcium.

Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis of the nematodes and thereby allow removal from the gastro-intestinal (GI) system by peristalsis.

Within the mammalian system febantel undergoes ring closure forming fenbendazole and oxfendazole. It is these chemical entities which exert the anthelmintic effect by inhibition of tubulin polymerisation. Formation of microtubules is thereby prevented, resulting in disruption of structures vital to the normal functioning of the helminth. Glucose uptake, in particular is affected, leading to a depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2-3 days later.

Pharmacokinetic particulars

After oral administration to dogs, praziquantel is extensively and quickly absorbed from the gastro-intestinal tract. Maximum plasma concentration of 752 µg/L is obtained in less than 2 hours. It is rapidly and extensively metabolised in the liver into hydroxylated derivatives of the parent compound, then rapidly eliminated, mainly in urine.

After oral administration to dogs, febantel is moderately absorbed from the gastro-intestinal tract. Febantel is rapidly metabolised in the liver into fenbendazole and its hydroxy and oxidative derivatives like oxfendazole. Maximum plasma concentration of fenbendazole (173 µg/L) is obtained after about 5 hours. Maximum plasma concentration of oxfendazole (147 µg/L) is obtained after about 7 hours. The excretion occurs mainly in the faeces.

After oral administration to dogs, pyrantel embonate is poorly absorbed. Maximum plasma concentration of 79 µg/L is obtained after about 2 hours. It is rapidly and extensively metabolised in the liver, then rapidly excreted, mainly in the faeces (the unchanged form) and in urine (the metabolites).

Marketing authorisation number

Vm 15052/4040

Vm 15052/4039

Marketing Authorisation Holder

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