

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear 3 in 1 Flavoured Wormer XL 525/504/175 mg Tablets for Large Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances	mg per tablet
Febantel	525.0
Pyrantel embonate	504.0
Praziquantel	175.0

Excipients

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet.

Pale brown to brown oval shaped tablet scored on both sides.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For the control of the following roundworms and tapeworms in adult dogs:

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. and *Dipylidium caninum* (adult and immature forms).

4.3 Contraindications

Do not use simultaneously with piperazine compounds as piperazine may block the action of pyrantel embonate contained in Bob Martin Clear 3 in 1

Flavoured Wormer XL 525/504/175 mg Tablets for Large Dogs. Other worming products may contain piperazine.

4.4 Special warnings for each target species

Dogs may become infected with worms by eating insects (including fleas and lice), birds, small rodents, rabbits or raw offal from affected sheep, goats and cattle. Dogs will continue to be re-infected unless the route of infection is controlled e.g. treating a flea infestation or preventing a dog from scavenging or hunting.

Echinococcus multilocularis is a tapeworm of foxes, dogs and cats which is common in parts of Europe. It can also infect humans potentially causing severe liver disease which can be fatal. To prevent *Echinococcus multilocularis* establishing in the UK and Ireland it is a requirement that all dogs must be treated with a product containing praziquantel before entering the country.

4.5 Special precautions for use

i) Special precautions for use in animals

Do not exceed the stated dose when treating pregnant bitches.

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

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

In the interests of good hygiene, persons administering the tablet directly to a dog or by adding it to the dog's food, should wash their hands afterwards.

iii) Other precautions

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases slight and transient digestive tract disorders such as vomiting and/or diarrhoea may occur. In individual cases these signs can be accompanied by nonspecific signs such as lethargy, anorexia or hyperactivity.

4.7 Use during pregnancy and lactation

Consult a veterinary surgeon before treating pregnant animals. Bob Martin Clear 3 in 1 Flavoured Wormer XL 525/504/175 mg Tablets for Large Dogs may be used during lactation (see Section 4.9 below).

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine.

4.9 Amounts to be administered and administration route

Dosage

The recommended dose rates are: 15 mg/kg bodyweight febantel, 14.4 mg/kg pyrantel and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 35 kg bodyweight. It is important to follow the treatment recommendations as presented here. Do not deviate from the recommendations without the advice of your veterinary surgeon.

Dogs of 35 kg bodyweight	1 Bob Martin Clear 3 in 1 Flavoured Wormer XL 525/504/175 mg Tablets for Large Dogs
--------------------------	---

Dogs of > 35 kg bodyweight	1 Bob Martin Clear 3 in 1 Flavoured Wormer XL 525/504/175 mg Tablets for Large Dogs plus the appropriate quantity of Bob Martin Clear 3 in 1 Flavoured Wormer 150/144/50 mg Tablets for Dogs equivalent to 1 tablet per 10 kg bodyweight
----------------------------	--

Administration and Duration of Treatment

Oral administration: the tablet(s) can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

For routine treatment a single dose is recommended.

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

For routine control adult dogs should be treated every 3 months. In case of suspected heavy roundworm infestation, please contact your veterinary surgeon for diagnosis and treatment recommendation

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Bob Martin Clear 3 in 1 Flavoured Wormer XL 525/504/175 mg Tablets for Large Dogs is well tolerated in dogs. In safety studies doses of 5 x or greater gave rise to occasional vomiting.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

The product contains anthelmintics active against roundworms and tapeworms. The product contains three active substances:

- 1) Febantel, a pro-benzimidazole, chemical name.
- 2) Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative, and
- 3) Praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative.

ATC VetCode: QP52AA51

5.1 Pharmacodynamic Properties

The product contains anthelmintics active against roundworms and tapeworms. The product contains three active substances: febantel, pyrantel embonate (pamoate) and praziquantel, a partially hydrogenated pyrazino-isoquinoline derivative used widely as an anthelmintic for both human and veterinary use.

Praziquantel is very rapidly absorbed and distributed throughout the parasite. Both *in vivo* and *in vitro* studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction and paralysis. 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 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 to 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.

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. There is no

known resistance to the active ingredients or the combination contained in Bob Martin Clear 3 in 1 Flavoured Wormer XL 525/504/175 mg Tablets for Large Dogs.

5.2 Pharmacokinetic Properties

Perorally administered praziquantel is absorbed almost completely from the intestinal tract. After absorption, the drug is distributed to all organs. Praziquantel is metabolized into inactive forms in the liver and secreted in bile. It is excreted within 24 hours to more than 95% of the administered dosage. Only traces of non-metabolised praziquantel are excreted.

Following administration of the product to dogs, peak plasma concentrations of praziquantel were achieved by approximately 2.5 hours.

The pamoate salt of pyrantel has low aqueous solubility, an attribute that reduces absorption from the gut and allows the drug to reach and be effective against parasites in the large intestine. Following absorption, pyrantel pamoate is quickly and almost completely metabolized into inactive metabolites that are excreted rapidly in the urine.

Febantel is absorbed relatively rapidly and metabolized to a number of metabolites including fenbendazole and oxfendazole, which have anthelmintic activity.

Following administration of the product to dogs, peak plasma concentrations of fenbendazole and oxfendazole were achieved by approximately 2-3 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Artificial beef flavour Irradiated
Maize starch
Lactose monohydrate
Microcrystalline cellulose
Povidone K25
Magnesium stearate
Sodium laurilsulfate
Silica colloidal anhydrous

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.
Any part-used tablets should be discarded.

6.5 Nature and composition of immediate packaging

Container material: PVC-coated aluminium foil
Container colour: White
Container sizes: Cartons containing 2, 10, 20, and 50 tablets
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4155

9. DATE OF FIRST AUTHORISATION

20 August 2002

10. DATE OF LAST REVISION OF THE TEXT

November 2020

Approved 05 November 2020

