

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear 3 in 1 Flavoured Wormer 150/144/50 mg Tablets for Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances	mg per tablet
Febantel	150
Pyrantel embonate	144
Praziquantel	50

Excipients

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet

Light brown to brown, round, flat divisible tablet, cross scored on one side

4. CLINICAL PARTICULARS

4.1 Target species

Dogs

4.2 Indications for use, specifying the target species

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

Ascarids:	<i>Toxocara canis</i> , <i>Toxascaris leonina</i> (adult and late immature forms).
Hookworms:	<i>Uncinaria stenocephala</i> , <i>Ancylostoma caninum</i> (adults)
Whipworms:	<i>Trichuris vulpis</i> (adults)
Tapeworms:	<i>Echinococcus spp.</i> , <i>Taenia spp.</i> , <i>Dipylidium caninum</i> (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 150/144/50 mg Tablets for 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 package leaflet to the physician.

In the interests of good hygiene, persons administering the tablet directly to the 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, lactation or lay

Consult a veterinary surgeon before treating pregnant animals.
Bob Martin Clear 3 in 1 Flavoured Wormer 150/144/50 mg Tablets for 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 compounds (see Section 4.3 above).

4.9 Amounts to be administered and administration route

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 10 kg (22 lbs) 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.

Puppies and Small
Dogs:

3-5 kg bodyweight	= ½ tablet
>5-10 kg bodyweight	= 1 tablet

Medium Dogs:

>10-15 kg bodyweight	= 1 ½ tablets
>15-20 kg bodyweight	= 2 tablets
>20-25 kg bodyweight	= 2 ½ tablets
>25-30 kg bodyweight	= 3 tablets

Large Dogs:

>30-35 kg bodyweight	= 3 ½ tablets
>35-40 kg bodyweight	= 4 tablets

For oral administration, the tablets can be given to the dog or disguised in 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. Not for use in dogs weighting less than 3 kg.

For the control of *Toxocara*, 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 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 150/144/50 mg Tablets for 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

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

1. Febantel, a probenzimidazole,
2. Pyrantel embonate (pamoate) a tetrahydropyrimidine derivative,
3. Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative

Pharmacotherapeutic Group: Anthelmintics, Quinoline derivatives and related substances.

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 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.

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 150/144/50 mg Tablets for Dogs.

5.2 Pharmacokinetic particulars

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 lauryl sulphate
Silica colloidal anhydrous

6.2 Major incompatibilities

None known

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years

6.4 Special precautions for storage

Do not store above 25°C
Any part used tablets should be discarded

6.5 Nature and composition of immediate packaging

Container:	Aluminium foil blister or polyethylene coated aluminium foil blister
Container colour:	Silver or white coloured
Container sizes:	Cartons containing 2, 4, 6 and 20 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 08007/4154

9. DATE OF FIRST AUTHORISATION

30 June 1989

10. DATE OF LAST REVISION OF THE TEXT

November 2020

Approved 05 November 2020

A handwritten signature in black ink, appearing to read "A. Hunter.", is positioned below the approval date.