SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

VetUK Flavoured Dog Wormer Tablets
50 mg Pyrantel, 50 mg Praziquantel, 150 mg Febantel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Praziquantel	50mg
Pyrantel	50mg (equivalent to 144 mg pyrantel embonate)
Febantel	150mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
A pale yellow tablet with a cross breakline on one side.
The tablets can be divided into halves or quarters.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

Treatment of the following gastrointestinal roundworms, tapeworms, hookworms and whipworms in dogs and puppies of the following species:

Roundworms: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).
Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).
Whipworms: *Trichuris vulpis* (adults).
Tapeworms: *Echinococcus* species, *(E. granulosus, E. multilocularis), Taenia* species, *(T. hydatigena, T. pisiformis, T. taeniformis), 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 VetUK Flavoured Dog Wormer. Other worming products may contain piperazine.Do not use in animals with a known

sensitivity to the active ingredients or to any of the excipients.

4.4 Special warnings for each target species

Fleas serve as intermediate hosts for one common type of tapeworm – *Dipylidium caninum*. Tapeworm infestation is certain to reoccur unless control of intermediate hosts such as fleas, mice, etc. is undertaken.
Tapeworm infestation is unlikely in pups less than 6 weeks of age.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.
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.

4.5 Special precautions for use

Special precautions for use in animals
Any part used tablet should be discarded.
To ensure administration of a correct dose, body weight should be determined as accurately as possible.
Do not exceed the stated dose when treating pregnant bitches.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental ingestion, seek medical advice and show the package leaflet or carton to the physician.
In the interests of good hygiene, persons administering the tablets directly to the dog, or by adding them to the dog's food, should wash their hands afterwards.

Other precautions
Echinococcosis represents a hazard for humans and is a notifiable disease according to the World Organisation for Animal Health (OIE). In the UK, suspected or confirmed Echinococcosis must be reported to the Animal and Plant Health Agency. Specific guidelines on Echinococcosis treatment, case follow-up, and any safeguards for people should 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.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- Common (more than 1 but less than 10 animals in 100 animals treated)
- Uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- Rare (more than 1 but less than 10 animals in 10,000 animals treated)
- Very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Consult a veterinary surgeon before treating pregnant animals. It is recommended that the product is not used in dogs during the first 4 weeks of pregnancy. Do not exceed the stated dose when treating pregnant bitches.Teratogenic effects attributed to high doses of febantel have been reported in sheep and rats. No studies have been performed in dogs during early pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine compounds (see section 4.3 above). Concurrent use with other cholinergic compounds can lead to toxicity.

4.9 Amounts to be administered and administration route

For oral administration only.

To ensure administration of a correct dose, body weight should be determined as accurately as possible.
The recommended dose rates are: 15mg/kg bodyweight febantel, 5 mg/kg pyrantel (equivalent to 14.4 mg/kg pyrantel embonate) 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.

Dosage table:

	Bodyweight (kg)	**Tablets**
Puppies and small dogs	3-5	½
	6-10	1
Medium dogs	11-15	1½
	16-20	2
	21-25	2½
	26-30	3
Large dogs	31-35	3½
	36-40	4
	>40	1 tablet per 10 kg

The tablets can be given directly 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 weighing 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

The combination of praziquantel, pyrantel embonate and febantel is well tolerated in dogs. In safety studies, a single dose of 5 times the recommended dose or greater gave rise to occasional vomiting.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic, praziquantel combinations.
ATC vet code: QP52AA51

5.1 Pharmacodynamic properties

This product contains anthelmintics active against gastrointestinal roundworms and tapeworms. The product contains three active substances, as follows:
1.Febantel, a probenzimidazole
2.Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative
3.Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative
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 vacuolization 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 gastrointestinal 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.

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 7-9 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Microcrystalline cellulose
Magnesium stearate
Colloidal anhydrous silica
Croscarmellose sodium
Sodium laurilsulfate
Pork flavour

6.2 Major incompatibilities

Not Applicable

6.3 Shelf life of the veterinary medicinal product as packaged for sale

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

6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions
Discard any unused half tablets immediately.

Do not remove tablets from immediate packaging until required for use.
Keep immediate packaging in outer carton

6.5 Nature and composition of immediate packaging

The product is presented in either:

Individual strips composed of aluminium foil 30 µm/30 gsm extruded polythene, containing 2 tablets.

or

Individual blisters composed of 45 µm, soft temper aluminium foil and 25 µm hard temper aluminium foil, containing 2 tablets.

The strips or blisters are packed into cartons containing 2 tablets.

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

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

C&H Generics Ltd
c/o Michael McEvoy and Co
Seville House
New Dock Street
Galway
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 40162/4015

9. DATE OF FIRST AUTHORISATION

10 March 2015

10. DATE OF REVISION OF THE TEXT

February 2020

Approved: 17 February 2020