1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DV8WORM 50 mg/ 144 mg/ 200 mg Tablets for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:
50 mg of Praziquantel
144 mg of Pyrantel embonate
200 mg of Fenbendazole

Excipients:

Qualitative composition of excipients and other constituents
Maize Starch
Microcrystalline cellulose
Lactose monohydrate
Povidone K30
Sodium starch glycolate (Type A)
Talc
Magnesium stearate
Colloidal anhydrous silica

Yellow or yellowish grey round scored tablets.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

Treatment of mixed infections by nematodes and cestodes of the following species and life stages of parasite:

Nematodes:

Ascarids: *Toxocara canis, Toxascaris leonina* (L5 and adults),
Hookworms: *Ancylostoma caninum, Uncinaria stenocephala* (adults),
Whipworms: *Trichuris vulpis* (adults).

Cestodes:
Tapeworms: *Dipylidium caninum, Taenia hydatigena, Taenia pisiformis*, *Echinococcus granulosus* (adult and late immature forms).

The veterinary medicinal product is exclusively indicated when use against gastrointestinal nematodes and cestodes is indicated at the same time.

3.3 Contraindications

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

3.4 Special warnings

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.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy.
Strategies that should be avoided because they might lead to an increased risk of development of resistance to anthelmintic drugs include:
- Too frequent and repeated use of anthelmintics from the same class over an extended period of time.
- Underdosing.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

3.5 Special precautions for use

Special precautions for safe use in the target species:

To minimise the risk of re-infestation and new infestation, excreta should be collected and properly disposed of for 24 hours following treatment.
Not to be used in puppies under 2 weeks of age or weighing less than 1 kg.
Treatment schedule:

The product should only be used in dogs when treatment of gastrointestinal nematodes and tapeworms is indicated at the same time. In the absence of the risk of mixed co-infestation, a narrower spectrum parasiticide must be used.

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

Partially unused half tablets should be returned to the open blister pack and stored in the carton.
In case of accidental ingestion, particularly by children, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to praziquantel, pyrantel embonate or fenbendazole should avoid contact with the veterinary medicinal product. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Echinococcus represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Health 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.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Vomiting, diarrhoea, lethargy, anorexia, hyperactivity.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during the early pregnancy in dogs. Do not use in pregnant bitches during the 1st and 2nd trimesters of pregnancy. After this time and during lactation use only according to the benefit-risk assessment by the responsible veterinarian.

Fertility:

In breeding dogs, use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonised.
Equally, do not administer together with organic phosphate esters and diethylcarbamazine.

3.9 Administration routes and dosage

Oral use.
Dosage:
The recommended dose is 1 tablet/10 kg bw (this is equivalent to 5 mg/kg praziquantel, 14.4 mg/kg pyrantel embonate and 20 mg/kg fenbendazole).
For routine treatment, a single dose is sufficient.
In case of a diagnosed helminthosis, the treatment should be repeated in 14 days. To ensure a correct dosage, body weight should be determined as accurately as possible.

Dog's body weight (kg)	Amount of tablets
Puppies and small dogs	
2-5	½
> 5-10	1
Medium size dogs	
>10-20	2
> 20-30	3
Large dogs	
>30-40	4

Method of administration:
The tablet can be given directly for oral administration or crushed and mixed into the feed.
The animal does not need to be fasted during the treatment.
For the control of *Toxocara canis*, nursing bitches should be dosed 2 weeks after giving birth and every two weeks until weaning.
In some cases, i.e. lactating bitches, young dogs (below 6 months of age) or in shelters, deworming frequency may be higher. In such cases, consult your veterinarian in order to establish an appropriate deworming protocol.
The need for and frequency of re-treatment should be determined on veterinary diagnosis, the local epidemiological situation and/or the epidemiological situation of other areas the dog has visited or is going to visit.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In target animal tolerance studies, vomiting has been reported in young animals receiving 3x the label dose for 6 consecutive days. No haematological or biochemical parameters have changed significantly, even at doses 5 times the recommended dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AA51

4.2 Pharmacodynamics

All active ingredients of the product have an antiparasitic effect with different mode of action. This veterinary medicinal product is a broad spectrum anthelmintic and is effective against the following species: *Toxocara canis*, *Toxascaris leonina*, *Ancylostoma caninum*, *Uncinaria stenocephala*, *Trichuris vulpis*, *Dipylidium caninum*, *Taenia hydatigena*, *Taenia pisiformis* and *Echinococcus granulosus* species.

In this fixed combination pyrantel and fenbendazole act synergistically against *Toxocara canis* in dogs.

Mechanism of action
Pyrantel, a tetrahydropyrimidine derivative and its embonate salt, has been a well-known wide-spectrum anthelminthic against the parasites in dogs. Pyrantel depolarises neuromuscular synapses. It also blocks the choline esterase enzyme. These cell biological changes cause a paralysis of the worms, and thus their death. Pyrantel embonate component is effective against gastrointestinal nematodes.

Praziquantel, an isoquinoline derivative, is a highly effective anthelminthic against a wide range of tapeworms species in dogs in adult and late immature forms. In particular, it includes *Dipylidium caninum*, *Taenia hydatigena*, *Taenia pisiformis* and *Echinococcus granulosus* (adult and late immature forms). Praziquantel is very rapidly absorbed through the parasite's surface and distributed throughout the parasite. 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.

Fenbendazole, a methyl-5(phenylthio)-2-benzimidazole carbamate, is a widely used benzimidazole compound (pharmacologically active metabolite of febantel). Mechanism of action is based on inhibition of polymerization of microtubules. Fenbendazole blocks the fumarate reductase enzyme in the worms, and blocks the glucose uptake, thus leading to damage of their energy-producing metabolic processes. This results in the exhaustion of the energy reserves, resulting in the paralysis of worms, and eventually its death. It is suitable for treatment against roundworms (ascarids, hookworms and whipworms).

4.3 Pharmacokinetics

Praziquantel is absorbed almost completely in the small intestine following oral administration to dogs. Absorption is very rapid reaching maximum serum levels within 0.5 to 2 hours. After absorption, the drug is widely distributed through the body. Plasma protein binding is high. Praziquantel is rapidly metabolised in the liver leading to inactive metabolites. In dogs, metabolites are eliminated by urine (66 % of an oral dose) and via the bile (15%) in the faeces. Elimination half-life in dogs is about 3 hours.

Pyrantel (as embonate), being a low water-soluble compound, is poorly absorbed in the gastrointestinal tract, reaching the final parts of the intestine. The absorbed drug is extensively metabolised and the parent compound/metabolites are excreted by urine.

After oral administration fenbendazole is absorbed slowly and only partially.
Following absorption from the digestive tract fenbendazole is metabolised in the liver to sulphoxide (oxfendazole) and further to sulphone and amine derivatives.
Fenbendazole and its metabolites disperse slowly throughout the body, reaching high concentrations in the liver. Unchanged and metabolised fenbendazole is excreted primarily (>90%) with the faeces, and to a small extent also via the urine and milk.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging (blister): use immediately.

5.3 Special precautions for storage

Store in a dry place, protect from light.
Store in the original package. Keep out of sight and reach of children.
Partially used half tablets to be returned to the blister/PE container for use at the next administration.

5.4 Nature and composition of immediate packaging

Immediate packaging material: PVC/Alu blister or polyethylene container.
Package size:

- carton box containing PVC/Alu blister of 1x2, 3x2, 1x10, 2x10, 10x10 and 20x10 tablets
- polyethylene container containing 200 tablets.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Duggan Veterinary Supplies Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10400/001/001

8. DATE OF FIRST AUTHORISATION

25 May 2022

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

27 August 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).