NOAH Compendium

Vetoquinol UK Ltd
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Drontal Oral Suspension for Puppies

Species:	Dogs
Therapeutic indication:	**Pharmaceuticals: Endoparasiticides:** Anthelmintics for dogs
Active ingredient:	Febantel, Pyrantel Embonate
Product:	Drontal® Oral Suspension for Puppies
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Presentation

A pale red suspension for oral administration. Each ml of suspension contains 5.0 mg pyrantel (as pyrantel embonate 14.4 mg) and 15 mg febantel. The product also contains 2.05 mg sodium benzoate (E211), 2.05 mg sodium propionate (E281) and 0.25 mg ponceau 4R (E124).

Uses

For the treatment of roundworm infections in puppies and young dogs up to one year of age caused by:

Ascarids	*Toxocara canis, Toxascaris leonina*
Hookworm	*Ancylostoma caninum, Uncinaria stenocephala*
Whipworm	*Trichuris vulpis*

Dosage and administration

The dose is 1 ml suspension/kg body weight (equivalent to 14.4 mg/kg pyrantel embonate and 15 mg/kg febantel).

Administration is by the oral route. The product may be given directly to the animal or mixed with the feed. No special dietary measures are necessary.

Mix the product by inversion of the container before withdrawing the required dose.

Through intrauterine and transmammary infection, ascarid infestation may occur in dogs at a very early age. For some animals, especially in case of severe infections, elimination of ascarids may be incomplete, and a potential risk of infections to humans can not be excluded. Where epidemiologically appropriate, it is recommended that treatment should be started at 2 weeks of age and should be performed repeatedly at suitable intervals (for example every two weeks) until weaning. Otherwise treatment should be based upon confirmed infection, for example the results of faecal examinations.

Use During Pregnancy and Lactation

This product is contra-indicated for pregnant and lactating bitches.

Contra-indications, warnings, etc

Do not use simultaneously with compounds containing piperazine.

Parasite resistance to any particular class of anthelmintic may develop following frequent repeated use of an anthelmintic of that class.

The safety of the product has not been assessed in puppies younger than 2 weeks and weighing less than 0.6 kg.

In very rare cases mild transient digestive tract signs (e.g., vomiting, diarrhoea) may occur.

The anthelmintic effects of both pyrantel (spastic paralysis) and piperazine (neuromuscular paralysis) may be antagonised when the two drugs are used together.

Doses of up to 5 times the therapeutic level of the product have been administered to puppies and young dogs without clinical signs of intolerance arising. At 10 times the recommended dose the first sign of intolerance – vomiting – was evident.

User safety

Wash hands after use.

Avoid direct contact with the skin and eyes.

In case of accidental spillage wash the affected area immediately with clean running water.

Environmental safety

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

After opening, store the product at a temperature not exceeding 25 ºC.

Do not use after expiry date.

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

Shelf-life after first opening the immediate packaging: 12 weeks.

Legal category

Legal category: NFA-VPS

Packaging quantities

White high density polyethylene bottles of 50 ml and 100 ml with a white polyethylene screw closure and colourless low density polyethylene adapter insert.

Devices supplied: 5ml transparent polypropylene syringe with rubber plunger.

Marketing Authorisation Holder (if different from distributor)

Marketing Authorisation Holder

Vetoquinol UK Ltd, Steadings Barn, Pury Hill Business Park, Towcester NN12 7LS

Further information

Fixed combination of two anthelmintics: a tetrahydropyrimidine derivative, pyrantel (as the embonate) and a pro-benzimidazole, febantel. ATCvet code QP52AF02.

In this fixed combination product, the pyrantel and febantel act synergistically against nematodes (ascarids, hookworms and whipworms) of dogs. In particular, the spectrum of activity covers *Toxocara canis, Ancylostoma caninum* and *Trichuris vulpis*. Published data are also available to confirm that *Toxascaris leonina* and *Uncinaria stenocephala* are also susceptible to this particular combination of actives.

Febantel, N-{2-[2,3-bis,(methoxycarbonyl)-guanidino]-5-(phenylthio) phenyl}-2-methoxyacetamide, is a pro-benzimidazole. 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 depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2-3 days later. Pyrantel, (E)-1,4,5,6-Tetrahydro-1-methyl-2-[2-(2-thienyl) vinyl] pyrimidine pamoate belongs to the tetrahydropyrimidine type. Its mode of action is to stimulate nicotinic cholinergic receptors inducing spastic paralysis and thereby allowing removal from the gastro-intestinal (GI) system by peristalsis.

Literature reports indicate after oral application of the recommended dose of 1 ml/kg bodyweight (corresponding to 14.4mg/kg pyrantel embonate and 15 mg/kg febantel) maximum serum concentrations for febantel were found between 1 and 6 hours with a C_{max} of 0.019 mg/l two hours after dosing. As febantel, as a pro-drug, is metabolised to fenbendazole which is further converted to oxfendazole, also these metabolites were measured. C_{max} of fenbendazole was 0.130 mg/l after 3 hours and C_{max} of oxfendazole was 0.157 mg/l at about 5 hours after application.

The C_{max} of pyrantel (measured as pyrantel base) was 0.084 mg/l 2.5 hours after application.

Marketing Authorisation Number

UK: Vm 08007/4166

Significant changes

GTIN

GTIN description:	Drontal Oral Suspension for Puppies (50ml)
GTIN:	04007221025023
GTIN description:	Drontal Oral Suspension for Puppies (100ml)
GTIN:	04007721025016