1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Drontal Oral Suspension for Puppies 15/5 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substances:

Febantel 15.00 mg
Pyrantel 5.00 mg (as pyrantel embonate 14.40mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium benzoate (E211)	2.05 mg
Sodium propionate (E281)	2.05 mg
Ponceau 4R (E124)	0.25 mg
Sodium dihydrogen phosphate dihydrate	
Sorbitan oleate (E494)	
Povidone K25 (E1202)	
Polysorbate 80 (E433)	
Docusate sodium	
Bentonite (E558)	
Citric acid anhydrous (E330)	
Xanthan gum (E415)	
Propylene glycol (E1520)	
Purified water	

Oral suspension.
Pale red suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs (puppies and young dogs up to one year of age).

3.2 Indications for use for each target species

For the treatment of roundworm infections caused by:

Ascarids: *Toxocara canis*
Toxascaris leonina

Hookworms: *Ancylostoma caninum*
Uncinaria stenocephala

Whipworm: *Trichuris vulpis*

3.3 Contraindications

Do not use simultaneously with compounds containing piperazine. See sections 3.7 and 3.8.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:
The safety of the veterinary medicinal product has not been assessed in puppies younger than 2 weeks and weighing less than 0.600 kg.

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

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Digestive tract disorder[1] (e.g. diarrhoea, vomiting)[1]

[1]Mild and transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative 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:

Do not use in pregnant and lactating bitches.

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

Oral use.

Dosage and treatment schedule

For a single oral administration 15 mg/kg bodyweight febantel and 5 mg/kg bodyweight pyrantel (as embonate) corresponding to 14.4 mg/kg pyrantel embonate, equivalent to 1 ml/kg bodyweight.

Through intrauterine and trans-mammary 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 cannot 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 2 weeks), until weaning. Otherwise, treatment should be based upon confirmed infection, for example the results of faecal examinations.

Method of administration

The veterinary medicinal product may be given directly to the animal or mixed with feed. No special dietary measures are necessary.
Mix the veterinary medicinal product by inversion of the container before drawing the required dose.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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

Doses of up to 5 times the therapeutic level of the veterinary medicinal 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.

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 : QP52AF02.

4.2 Pharmacodynamics

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, Ancyclostoma 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 polymerization. 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 paralysis.

4.3 Pharmacokinetics

Literature reports indicate after oral application of the recommended dose of 1 ml/kg bodyweight (corresponding to 14.4 mg/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 fenbendazol which is further converted to oxfendazole, also these metabolites were measured. C_{max} of febendazole 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 12 weeks.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
After opening the immediate package, do not store above 25 ºC.

5.4 Nature and composition of immediate packaging

Material of the primary container:	White high density polyethylene bottle White polypropylene screw closure Colourless low density polyethylene adapter insert
Container volumes:	50 ml, 100 ml
Devices supplied (if relevant)	5ml transparent polypropylene syringe with rubber plunger

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

Vetoquinol SA,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10521/008/001

8. DATE OF FIRST AUTHORISATION

23/05/2008

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

13/10/2025

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).