1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Member State	Proposed name
AT	Drontal Junior
DE	Welpan für Welpen und junge Hunde
EE	Drontal Puppy
FI	Welpan vet
FR	Dronstop Chiot
ES	Drontal suspensión oral para cachorros y perros jóvenes
IE	Drontal Oral Suspension for Puppies
IS	Welpan vet
LT	Drontal Puppy
LV	Drontal Puppy
NO	Welpan vet
UK	Drontal Oral Suspension for Puppies

15/5 mg/ml
Oral Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

Active substances:

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

Excipients:

Sodium benzoate (E211)	2.05mg
Sodium propionate (E281)	2.05mg
Ponceau 4R (E124)	0.25mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension
Pale red suspension

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

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

Ascarids:	Toxocara canis
	Toxascaris leonina
Hookworms:	Ancylostoma caninum
	Uncinaria stenocephala
Whipworm:	Trichuris vulpis

4.3 Contraindications

Do not use simultaneously with compounds containing piperazine. See sections 4.7 and 4.8.

4.4 Special warnings

None

4.5 Special precautions for use

Special precautions for use in animals

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 0.600 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.

Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant and lactating bitches.

4.8 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.

4.9 Amounts to be administered and administration route

Dosage and Treatment Schedule

For a single oral adminstration 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 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.

Method of Administration

Oral administration. The product may be given directly to the animal or mixed with feed. No special dietary measures are necessary.

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Fixed combination of two anthelmintics: a tetrahydro-pyrimidine derivative, pyrantel (as the embonate) and a pro-benzimidazole, febantel.

ATCvet code QP52AF02.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium propionate (E281)
Sodium benzoate (E211)

Sodium dihydrogen phosphate dihydrate
Sorbitan oleate (E494)
Povidone K25 (E1202)
Polysorbate 80 (E433)
Docusate sodium
Bentonite (E558)
Citric acid anhydrous (E330)
Ponceau 4R (E124)
Xanthan gum (E415)
Propylene glycol (E1520)
Purified water

6.2 Incompatibilities

None known

6.3 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

6.4. Special precautions for storage

Do not use after expiry date.

This unopened veterinary medicinal product does not require any special storage conditions. After opening, store the product at a temperature not exceeding 25 ºC.

6.5 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 (Not all pack sizes may be marketed)
Devices supplied (if relevant)	5ml transparent polypropylene syringe with rubber plunger

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed in accordance with national requirements after conclusion of the MR phase]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed in accordance with national requirements after conclusion of the MR phase]

10 DATE OF REVISION OF THE TEXT

[To be completed in accordance with national requirements after conclusion of the MR phase]

PROHIBITION OF SALE, SUPPLY AND/OR USE

[To be completed in accordance with national requirements after conclusion of the MR phase]