

## FREEDOM OF INFORMATION SUMMARY

### I. GENERAL INFORMATION

#### A. File Number

NADA 141-007

#### B. Sponsor

Bayer Corporation  
Agriculture Division  
Animal Health Products  
P.O. Box 390  
Shawnee Mission, Kansas 66201

#### C. Proprietary Name

Drontal™ Plus Broad Spectrum Anthelmintic Tablets

#### D. Established Name

Praziquantel + Pyrantel Pamoate + Febantel

#### E. Dosage Form

Drontal(TM) Plus (praziquantel/pyrantel pamoate/febantel) Broad Spectrum Anthelmintic Tablets are available in two sizes. Each size is scored for convenient oral administration.

#### F. Amount of Active Ingredient

Each Drontal(TM) Plus Tablet for Medium and Large Dogs contains 68.0 mg praziquantel, 68.0 mg pyrantel base as pyrantel pamoate and 340.2 mg febantel.

Each Drontal(TM) Plus Tablet for Small Dogs contains 22.7 mg praziquantel, 22.7 mg pyrantel base as pyrantel pamoate and 113.4 mg febantel.

#### G. Dispensing Status

Rx

#### H. Dosage Regimen

DOSAGE CHARTS

**Table 1. Drontal(TM) Plus Tablets for Small Dogs\* (2-25 lbs.)**

Body Wt. (lbs.)	Number of Tablets
2 - 4	0.5
5 - 7	1.0
8 - 12	1.5
13 - 18	2.0
19 - 25	2.5

**Table 2. Drontal(TM) Plus Tablets for Medium & Large Dogs (26 lbs. and over)**

<b>Body Wt. (lbs.)</b>	<b>Number of Tablets</b>
26 - 30	1.0
31 - 44	1.5
45 - 60	2.0
61 - 74	2.5
75 - 90	3.0
91 - 104	3.5
105 - 120	4.0

\*NOT FOR USE IN DOGS WEIGHING LESS THAN 2 LBS. OR PUPPIES LESS THAN 3 WEEKS OF AGE. Tablets may be given directly by mouth or offered in a small amount of food. Fasting is neither necessary nor recommended prior to or after treatment.

**I. Indication**

Tapeworms (*Dipylidium caninum*, *Taenia pisiformis*, *Echinococcus granulosus*, and *Echinococcus multilocularis*), hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*), ascarids (*Toxocara canis* and *Toxascaris leonina*), and whipworms (*Trichuris vulpis*).

**J. Effect of Supplement**

This supplemental application amends NADA 141-007, Drontal™ Plus Broad Spectrum Anthelmintic Tablets, by adding the tape-worm *Echinococcus multilocularis* claim to the label.

**II. EFFECTIVENESS**

Efficacy of Drontal(TM) Plus (praziquantel/pyrantel pamoate/febantel) Broad Spectrum Anthelmintic Tablets [59 FR 33908, July 1, 1994] against *E. multilocularis* in dogs is based on the scientific data described in the Freedom of Information (FOI) Summary for Droncit (praziquantel) Tablets [NADA 111-798, 58 FR 42852-3, Aug. 12, 1993].

*Echinococcus granulosus* and *Echinococcus multilocularis* are classified in the same genus. The laboratory data described in the FOI Summary of NADA 111-798 indicate that Droncit (praziquantel) Tablets [NADA 111-798, 58 FR 42852-3, Aug. 12, 1993] is 100% efficacious against both *E. granulosus* and *E. multilocularis*. The FOI Summary for the three-way combination Drontal (TM) Plus (praziquantel/pyrantel pamoate/febantel) Broad Spectrum Anthelmintic Tablets (59 FR 33908, July 1, 1994) states that neither pyrantel nor febantel interfered with the activity of praziquantel against *E. granulosus*.

Since *E. granulosus* and *E. multilocularis* are classified in the same genus, Droncit (praziquantel) Tablets [NADA 111-798, 58 FR 42852-3, Aug. 12, 1993] demonstrated 100% efficacy against both *E. granulosus* and *E. multilocularis* in laboratory studies, and no interference was demonstrated in the three-way combination product, it is concluded that praziquantel in Drontal(TM) Plus (praziquantel/pyrantel pamoate/febantel) Broad

Spectrum Anthelmintic Tablet is as efficacious as the Droncit (praziquantel) Tablet against *E. multilocularis*.

### **III. TARGET ANIMAL SAFETY**

Animal safety is cross referenced to the existing, original Freedom of Information Summary for Drontal(TM) Plus (praziquantel/pyrantel pamoate/febantel) Broad Spectrum Anthelmintic Tablets (59 FR 33908, July 1, 1994] . The original FOI Summary describes the safety studies that were conducted to support the approval of this product.

### **IV. HUMAN FOOD SAFETY**

Human safety is cross referenced to the existing, original Freedom of Information Summary for Drontal(TM) Plus (praziquantel/pyrantel pamoate/febantel) Broad Spectrum Anthelmintic Tablets (59 FR 33908, July 1,1994].

### **V. AGENCY CONCLUSIONS**

The data in support of this supplemental New Animal Drug Application complies with the requirements of Section 512 of the Act and Section 514.111 of the implementing regulations. When used under the labeled conditions of use, the data demonstrates that Drontal(TM) Plus (praziquantel/pyrantel pamoate/febantel) Broad Spectrum Anthelmintic Tablets (59 FR 33908, July 1, 1994] are safe and effective in the treatment of dogs with *Echinococcus multilocularis*.

Since the approval of this supplement utilized studies conducted with another formulation of praziquantel [Droncit (praziquantel) Tablets, NADA 111-798, 58 FR 42852-3, Aug. 12, 1993], the addition of *E. multilocularis* as a claim on the label does not extend the original exclusivity period for Drontal(TM) Plus (praziquantel/pyrantel pamoate/febantel) Broad Spectrum Anthelmintic Tablets which began May 19, 1994 (59 FR 33908, July 1, 1994].

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.