ANNEX I:

List of the names, pharmaceutical form, strength of the veterinary medicinal products, animal species, route of administration marketing authorisation holder in the Member States.

Mamber State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Austria	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Austria	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Belgium	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Belgium	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Belgium	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Bulgaria	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus таблетки за кучета	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Bulgaria	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus таблетки за кучета	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Bulgaria	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus таблетки за кучета	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Member State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Cyprus	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus Διακία Για Σκύλους	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Czech Republic	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tablety pro psy	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Czech Republic	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tablety pro psy	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Czech Republic	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tablety pro psy	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Denmark	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Denmark	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Estonia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tabletid koertele	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Estonia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tabletid koertele	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Member State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Finland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus 50 mg/ 144 mg/ 150 mg tablet	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Finland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus 50 mg/ 144 mg/ 150 mg tablet	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Finland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus 50 mg/ 144 mg/ 150 mg tablet	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
France	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Milaxyn comprimé pour chiens	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
France	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Strantel comprimé pour chiens	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
France	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazical comprimé pour chiens	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
France	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Voxical comprimé pour chiens	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Member State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Germany	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Germany	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Germany	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Strantel Tabletten für Hunde	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Greece	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel plus Δισκία Για Σκύλους	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Greece	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel plus Δισκία Για Σκύλους	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Greece	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel plus Δισκία Για Σκύλους	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Hungary	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tabletta kutyák részére A.U.V	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Member State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Hungary	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tabletta kutyák részére A.U.V	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Hungary	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tabletta kutyák részére A.U.V	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Iceland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus töflur fyrir hunda	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Iceland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus töflur fyrir hunda	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Milaxyn Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Member State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazical Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Strantel Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Voxical Plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Italy	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Canitel Plus compresse per cani	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Italy	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus compresse per cani	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Italy	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel compresse per cani	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Member State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Latvia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel tablets Tabletes suņiem	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Latvia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel tablets Tabletes suņiem	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Latvia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel tablets Tabletes suņiem	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Lithuania	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tabletės šunims	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Lithuania	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tabletės šunims	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Lithuania	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tabletės šunims	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Luxembourg	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tabletten voor honden	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Member State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Luxembourg	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tabletten voor honden	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Netherlands	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tabletten voor honden	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Netherlands	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tabletten voor honden	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Netherlands	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tabletten voor honden	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Norway	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Vet	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Norway	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Vet	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Poland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tabletki dla psów	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Member State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Poland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tabletki dla psów	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Poland	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tabletki dla psów	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Portugal	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus Comprimidos para cães	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Portugal	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus Comprimidos para cães	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Portugal	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus Comprimidos para cães	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Romania	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus Comprimate pentru câini	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Romania	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus Comprimate pentru câini	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Member State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Romania	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus Comprimate pentru câini	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Slovakia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tablety pre psov	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Slovakia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tablety pre psov	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Slovakia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tablety pre psov	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Slovenia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel Plus tablete za pse	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Slovenia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel Plus tablete za pse	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Slovenia	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel Plus tablete za pse	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Member State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
Spain	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel comprimidos para perros	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Spain	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel comprimidos para perros	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Spain	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel comprimidos para perros	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Sweden	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Exitel vet. 150 mg/144 mg/50 mg tablett för hund	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
Sweden	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Strantel vet. 150 mg/144 mg/50 mg tablett för hund	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
United Kingdom	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Cazitel plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs
United Kingdom	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Easimax plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Member State EU/EEA	Marketing authorisation holder	Name	INN/Strength	Pharmaceutical form	Animal species
United Kingdom	Chanelle Pharmaceuticals Manufacturing Ltd. IE-Loughrea Co. Galway Ireland	Prazitel plus tablets for dogs	Praziquantel 50 mg Pyrantel 50 mg (equivalent to 144 mg pyrantel embonate) Febantel 150 mg	Tablet	Dogs

Annex II

Scientific conclusions and grounds for amendment of the summary of product characteristics, labelling and package leaflet

Overall summary of the scientific evaluation of Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus, Prazitel Plus and associated names *(see annex I)*

1. Introduction

Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus, Prazitel Plus and associated names are tablets for dogs containing praziquantel, pyrantel embonate and febantel and indicated for various parasitic infections. The products concerned are seven duplicates with identical hybrid application dossiers for which the reference product is Drontal Plus (Bayer Animal Health). The marketing authorisation holder for the concerned product is Chanelle Pharmaceuticals Manufacturing Ltd. Prazitel Plus, Exitel Plus, Cazitel Plus and associated names were authorised in many Member States (EU/EEA) by mutual recognition procedure (MRP) IE/V/0241-0243/001/MR as duplicate hybrid applications under Article 13(3) of Directive 2001/82/EC as amended. The SPC for these three products includes indications against *Echinococcus granulosus* and *Echinococcus multilocularis*. Milaxyn Plus, Strantel Plus, Prazical Plus and Voxical Plus were authorised subsequently by MRP IE/V/0272-0275/001/MR as hybrid applications under Article 13(3) of Directive 2001/82/EC, as amended involving Ireland as reference Member State and France as concerned Member State. The SPCs for these four products does not include indications against *Echinococcus granulosus* and *Echinococcus multilocularis*.

The aim of the referral is to resolve divergences between the SPCs for the above mentioned products and thus to harmonise the different SPCs across the EU. The main difference between the SPCs for the products relates to the claim regarding efficacy against *Echinococcus granulosus* and *Echinococcus multilocularis* and use of the product in pups less than 9 weeks of age and dogs weighing less than 2.5 kg.

The CVMP requested Chanelle Pharmaceuticals Manufacturing Ltd.to justify the claim for efficacy against *Echinococcus* species and to provide all relevant data in support of the *Echinococcus* claim, which were presented previously in the dossiers submitted for marketing authorisation, together with comments on the suitability of the documentation to support the extrapolation of efficacy from the reference product to the hybrid product. In addition the Chanelle Pharmaceuticals Manufacturing Ltd.was requested to provide a proposal for harmonised product information and supportive data for the harmonised product information.

2. Discussion of the data available

The bibliographic data provided by the marketing authorisation holder confirmed the well established efficacy of praziquantel at a dose of 5 mg/kg against *E. granulosus* and *E. multilocularis*. While the majority of references cited by Chanelle Pharmaceuticals Manufacturing Ltd.reported on the efficacy of praziquantel when presented as a monosubstance tablet (Droncit, Bayer Animal Health), a number of the references reported on the efficacy of praziquantel when presented in other pharmaceutical forms (injectable, paste, powder) and/or for administration by other routes (intramuscular, subcutaneous) and/or when combined with other active substances (e.g. Drontal Plus, Bayer Animal Health). Regardless of the administration route and the formulation, praziquantel at a dose of 5 mg/kg bw was consistently shown to be up to 100% effective against immature and mature forms of *E. granulosus* and *E. multilocularis*. In a number of the studies reported, praziquantel was shown to be highly effective against *E. granulosus* and *E. multilocularis* at doses less than 5 mg/kg bw.

Chanelle Pharmaceuticals Manufacturing Ltd.has extrapolated the efficacy data available in the public domain for the Bayer Animal Health products (Droncit and Drontal Plus) to the concerned product (Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus and Prazitel Plus and associated names) by presenting a comparative pharmacokinetic study conducted with the concerned product and Drontal Plus (Bayer Aniamal Health). Based on the findings of this study, the test and reference products can be considered equivalent with respect to AUC_{inf} of praziquantel; therefore similar systemic availability can be assumed. While plasma concentrations are not a direct measure of the concentrations of active available locally in the gastro intestinal tract, it is considered that similar systemic availability (similar extent of absorption) is indicative of similar behaviour locally in the gastro intestinal tract following product administration. These data suggest that the test product is likely to be at least as effective as the reference product. These data are adequate as a bridge between the documented efficacy of the reference product (Drontal Plus) and the concerned product (Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus and Prazitel Plus and associated names).

The *in vivo* data are further supported by the results of the comparative dissolution profiles of the concerned product with the reference product Drontal Plus tablets. These *in vitro* data confirm that, under the conditions tested, the dissolution profiles are similar for both products.

Based on the totality of information presented, it is considered that the efficacy of the concerned product will be similar to that of the reference product, Drontal Plus. In further support of the safety and efficacy of the product, Chanelle Pharmaceuticals Manufacturing Ltd.provided pharmacovigilance data for Prazitel Plus and related duplicate products which include in the SPC the claim for efficacy against *Echinococcus*. Prazitel Plus was first launched in the EU market in May 2009. Since first marketing, the product has been shown to be well tolerated (very few reports of adverse effects) and there have been no reports of suspected lack of expected efficacy. The product continues to have a positive benefit - risk balance.

In conclusion, based on the totality of data presented, it is accepted that the concerned product (Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus and Prazitel Plus and associated names) will be effective (up to 100%) in the treatment of immature and mature forms of *E. granulosus* and *E. multilocularis* in the dog.

The indication for the treatment of immature and mature forms of *E. granulosus* and *E. multilocularis* can be accepted for the concerned product (Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus and Prazitel Plus and associated names).

A target animal safety study confirmed that the concerned product (Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, Exitel Plus, Cazitel Plus, Prazitel Plus and associated names) is well tolerated when administered to pups (9 weeks of age) at doses up to five times the recommended treatment dose or when administered at the recommended treatment dose for up to three days.

While the tolerance study was not performed on puppies less than 9 weeks of age, there is no reason to expect that this product presents an unacceptable risk to younger puppies. There is extensive literature for the individual active substances and the combination which supports the safety of this product in younger puppies. The products have been formulated to have the same composition, in terms of active substances, as the authorised reference product and the proposed conditions of use of the products are identical to those of the reference product. Therefore, it can be assumed that the concerned product is unlikely to present any greater risk to the target animal relative to that posed by the reference product. The reference product is authorised for use from two weeks of age with no specific risk identified for this particular age group.

In view of the above, the CVMP considers use in puppies less than 9 weeks of age or dogs less than 2.5 kg is unlikely to give rise to a safety concern, therefore a restriction on use in such animals is unnecessary.

3. Benefit-Risk Assessment

The products are tablets for dogs containing praziquantel, pyrantel embonate and febantel and indicated for various parasitic infections. The products concerned are seven duplicates with identical hybrid application dossiers for which the reference product is Drontal Plus.

Benefit assessment

Direct benefits

Based on the available efficacy data, it is accepted that the concerned product will be effective (up to 100%) in the treatment of immature and mature forms of *E. granulosus* and *E. multilocularis* in the dog.

The product is considered to be effective for the treatment of mixed infections by nematodes and cestodes of the following species:

Nematodes:

Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).

Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).

Whipworms: *Trichuris vulpis* (adults).

Cestodes:

Tapeworms*: Echinococcus* species*, (E. granulosus, E. multilocularis),* Taenia species*, (T. hydatigena, T. pisiformis, T. taeniformis),* Dipylidium caninum *(*adult and immature forms*).*

The target parasites have the potential to impact on welfare of individual infected animals. In addition, a number of the target parasites have the potential to infect humans (zoonotic potential). Therefore, use of the product to eliminate the target parasites will benefit both the treated animal and public health.

Risk assessment

The product is well tolerated in the target species. The Committee considered on basis of a target animal safety study that the use of the concerned product in puppies less than 9 weeks of age or dogs less than 2.5 kg is unlikely to give rise to a safety concern and therefore a restriction on use in such animals is unnecessary. This conclusion is in line with the view taken during the various mutual recognition procedures (IE/V/0241-0243/001/MR).

The product is not expected to pose a risk to the user when used in accordance with label recommendations. Appropriate user safety advice is included in the product literature.

The products are not expected to pose a risk to the environment.

Evaluation of the benefit - risk balance

It is considered that the claimed efficacy of the product has been adequately substantiated. Further, it is considered that use of this product, in accordance with label recommendations in the product literature, sufficiently manages the risk associated with its use.

The overall benefit - risk balance is considered positive.

Grounds for amendment of the summary of product characteristics, labelling and package leaflet

Whereas

- the CVMP considered the primary scope of the referral regarding efficacy against *Echinococcus granulosus* and *Echinococcus multilocularis*;
- the CVMP considered the in use of the products in puppies less than 9 weeks of age and dogs weighing less than 2.5 kg
- the CVMP reviewed the summary of products characteristics, labelling and package leaflet proposed by the marketing authorisation holder and considered all the overall submitted data;

the CVMP, concluded that the overall benefit/risk balance for these products remains positive subject to the recommended changes in the product information for Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, and associated names, authorised by MRP IE/V/0272-0275/001/MR involving Ireland as reference Member State and France as concerned Member State. Therefore the CVMP has recommended the variation of the marketing authorisations for which the summaries of product characteristics, labelling and package leaflet are set out in Annex III for Milaxyn Plus, Strantel Plus, Prazical Plus, Voxical Plus, and associated names, authorised by MRP IE/V/0272-0275/001/MR involving Ireland as reference Member State and France as concerned Member State *(see Annex I)*. The marketing authorisations for Prazitel Plus, Exitel Plus, Cazitel Plus and associated names, authorised by MRP IE/V/0241-0243/001/MR *(see Annex I)* do not need to be amended.

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substances:

Praziquantel	50mg
Pyrantel	50mg (equivalent to 144 mg pyrantel embonate)
Febantel	150mg

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
A pale yellow tablet with a cross breakline on one side.
The tablets can be divided into equal halves or equal quarters.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

In dogs: Treatment of mixed infections by nematodes and cestodes of the following species
Nematodes:
Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).
Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).
Whipworms: *Trichuris vulpis* (adults).
Cestodes:
Tapeworms: *Echinococcus* species, *(E. granulosus, E. multilocularis), Taenia* species, *(T. hydatigena, T. pisiformis, T. taeniformis), Dipylidium caninum* (adult and immature forms).

4.3 Contraindications

Do not use simultaneously with piperazine compounds.
Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
Any part used tablet should be discarded.
To ensure administration of a correct dose, body weight should be determined as accurately as possible

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In case of accidental ingestion, seek medical advice and show the package leaflet to the physician.
In the interests of good hygiene, persons administering the tablets directly to the dog, or by adding them to the dog's food, should wash their hands afterwards.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Teratogenic effects attributed to high doses of febantel have been reported in sheep and rats. No studies have been performed in dogs during early pregnancy. Use of the product during pregnancy should be in accordance with a benefit risk assessment by the responsible veterinarian. It is recommended that the product is not used in dogs during the first 4 weeks of pregnancy. Do not exceed the stated dose when treating pregnant bitches.

4.8 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 antagonized.
Concurrent use with other cholinergic compounds can lead to toxicity.

4.9 Amounts to be administered and administration route

For oral administration only.

The recommended dose rates are: 15mg/kg bodyweight febantel, 5 mg/kg pyrantel (equivalent to 14.4 mg/kg pyrantel embonate) and 5 mg/kg praziquantel. This is equivalent to 1 tablet per 10 kg (22 lbs) bodyweight.
The tablets can be given directly to the dog or disguised in food. No starvation is needed before or after treatment.

If there is a risk for re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration..

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

The combination of praziquantel, pyrantel embonate and febantel is well tolerated in dogs. In safety studies, a single dose of 5 times the recommended dose or greater gave rise to occasional vomiting.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic, praziquantel combinations.
ATC vet code: QP52AA51

5.1 Pharmacodynamic properties

This product contains anthelmintics active against gastrointestinal roundworms and tapeworms.
The product contains three active substances, as follows:
Febantel, a probenzimidazole
Pyrantel embonate (pamoate), a tetrahydropyrimidine derivative
Praziquantel, a partially hydrogenated pyrazinoisoquinoline derivative
In this fixed combination, pyrantel and febantel act against all relevant nematodes (ascarids, hookworms, and whipworms) in dogs. In particular, the activity spectrum covers *Toxocara canis*, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum* and *Trichuris vulpis*.

This combination shows synergistic activity in the case of hookworms and febantel is effective against *T. vulpis*.
The spectrum of activity of praziquantel covers all important cestode species in dogs, in particular *Taenia* spp., *Dipylidium caninum*, *Echinococcus granulosus* and *Echinococcus multilocularis*. Praziquantel acts against all adult and immature forms of these parasites.

Praziquantel is very rapidly absorbed through the parasite's surface and distributed throughout the parasite. Both in vitro and in vivo studies have shown that 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.
Pyrantel acts as a cholinergic agonist. Its mode of action is to stimulate nicotinic cholinergic receptors of the parasite, induce spastic paralysis of the nematodes and thereby allow removal from the gastrointestinal system by peristalsis.
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 of structures vital to the normal functioning of the helminth. Glucose uptake in particular is affected, leading to a depletion in cell ATP. The parasite dies upon exhaustion of its energy reserves, which occurs 2 – 3 days later.

5.2 Pharmacokinetic particulars

Perorally administered praziquantel is absorbed almost completely from the intestinal tract. After absorption, the drug is distributed to all organs. Praziquantel is metabolized into inactive forms in the liver and secreted in bile. It is excreted within 24 hours to more than 95% of the administered dosage. Only traces of non-metabolised praziquantel are excreted.
Following administration of the product to dogs, peak plasma concentrations of praziquantel were achieved by approximately 2.5 hours.

The pamoate salt of pyrantel has low aqueous solubility, an attribute that reduces absorption from the gut and allows the drug to reach and be effective against parasites in the large intestine. Following absorption, pyrantel pamoate is quickly and almost completely metabolized into inactive metabolites that are excreted rapidly in the urine.
Febantel is absorbed relatively rapidly and metabolized to a number of metabolites including fenbendazole and oxfendazole, which have anthelmintic activity.
Following administration of the product to dogs, peak plasma concentrations of fenbendazole and oxfendazole were achieved by approximately 7-9 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate,
Microcrystalline cellulose,
Magnesium stearate,
Colloidal anhydrous silica,
Croscarmellose sodium,
Sodium laurilsulfate
Pork flavour

6.2 Incompatibilities

Not Applicable

6.3 Shelf life of the veterinary medicinal product as packaged for sale

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Discard any unused divided tablets.

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions

6.5 Nature and composition of immediate packaging

The product is presented in either:

Individual strips composed of aluminium foil 30 µm/30 gsm extruded polythene, containing 2, 4, 6, 8, 10, 12, 14, 16, 18 or 20 tablets.

or

Individual blisters composed of 45 µm, soft temper aluminium foil and 25 µm hard temper aluminium foil, containing 2 or 8 tablets.

The strips or blisters are packed into cartons containing either 2,4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 70, 80, 84, 90, 98, 100, 104, 106, 120, 140, 150, 180, 200, 204, 206, 250, 280, 300, 500 or 1000 tablets.

Not all pack sizes may be marketed.

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 material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Limited,
Loughrea,
Co. Galway,
Ireland.

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed nationally.

10. DATE OF REVISION OF THE TEXT

To be completed nationally.

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

Labelling

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 2, 4, 6 AND 8 TABLETS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

50 mg/tablet Praziquantel, 50 mg/tablet Pyrantel (equivalent to 144 mg pyrantel embonate) and 150 mg/tablet Febantel.

3. PHARMACEUTICAL FORM

Pork flavoured tablets.

4. PACKAGE SIZE

2, 4, 6, 8 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

In dogs: Treatment of mixed infections by nematodes and cestodes.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For oral administration.
1 tablet per 10 kg bodyweight.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.
Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice

etc. is undertaken.
Tapeworm infestation is unlikely in pups less than 6 weeks of age.
Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.
Teratogenic effects attributed to high doses of febantel have been reported in sheep and rats. No studies have been performed in dogs during early pregnancy. Use of the product during pregnancy should be in accordance with a benefit risk assessment by the responsible veterinarian. It is recommended that the product is not used in dogs during the first 4 weeks of pregnancy. Do not exceed the stated dose when treating pregnant bitches.

10. EXPIRY DATE

EXP {month/year}
Discard any unused divided tablets.

11. SPECIAL STORAGE CONDITIONS

Do not use after expiry date.
This veterinary medicinal product does not require any special storage conditions

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Please refer to package leaflet for disposal advice.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway.
Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

BN{number}

<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>

{CARTON FOR PACK SIZES OF 10 TABLETS, AND UPWARDS}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

50 mg/tablet Praziquantel, 50 mg/tablet Pyrantel (equivalent to 144 mg pyrantel embonate) and 150 mg/tablet Febantel.

3. PHARMACEUTICAL FORM

Pork flavoured tablets.

4. PACKAGE SIZE

10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 70, 80, 84, 90, 98, 100, 104, 106, 120, 140, 150, 180, 200, 204, 206, 250, 280, 300, 500 and 1000 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

In dogs: Treatment of mixed infections by nematodes and cestodes of the following species
Nematodes:
Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).
Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).
Whipworms: *Trichuris vulpis* (adults).
Cestodes:
Tapeworms: *Echinococcus* species, *(E. granulosus, E. multilocularis), Taenia* species, *(T. hydatigena, T. pisiformis, T. taeniformis) Dipylidium caninum* (adult and immature forms).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

Read the package leaflet before use.
To ensure administration of a correct dose, body weight should be determined as accurately as possible

1 tablet per 10kg (22lbs) bodyweight. The tablets can be given directly to the dog or disguised in food. No starvation is needed before, or after, treatment.

Dosage table:

Bodyweight (kg)	**Tablets**
½ - 2	1/4
3-5	½
6-10	1
11-15	1½
16-20	2
21-25	2½
26-30	3
31-35	3½
36-40	4
>40	1 tablet per 10 kg

If there is a risk for re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.
Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.
Tapeworm infestation is unlikely in pups less than 6 weeks of age.
Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.
Teratogenic effects attributed to high doses of febantel have been reported in sheep and rats. No studies have been performed in dogs during early pregnancy. Use of the product during pregnancy should be in accordance with a benefit risk assessment by the responsible veterinarian. It is recommended that the product is not used in dogs during the first 4 weeks of pregnancy. Do not exceed the stated dose when treating pregnant bitches.

10. EXPIRY DATE

EXP {month/year}
Discard any unused divided tablets.

11. SPECIAL STORAGE CONDITIONS

Do not use after expiry date.
This veterinary medicinal product does not require any special storage conditions

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Please refer to package leaflet for disposal advice.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway.
Ireland.

16. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

17. MANUFACTURER'S BATCH NUMBER

BN{number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{BLISTER FOIL TEXT}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.
Praziquantel, Febantel, Pyrantel.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

3. BATCH NUMBER

BN {number}

4. EXPIRY DATE

EXP {month/year}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only.

PACKAGE LEAFLET

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway.
Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

To be completed nationally.

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

1 pork flavoured tablet contains 50 mg Praziquantel, 50 mg Pyrantel (equivalent to 144 mg pyrantel embonate) and 150 mg Febantel.

4. INDICATION(S)

In dogs: Treatment of mixed infections by nematodes and cestodes of the following species
Nematodes:
Ascarids: *Toxocara canis*, *Toxascaris leonina* (adult and late immature forms).
Hookworms: *Uncinaria stenocephala*, *Ancylostoma caninum* (adults).
Whipworms: *Trichuris vulpis* (adults).
Cestodes:
Tapeworms: *Echinococcus* species, *(E. granulosus, E. multilocularis), Taenia* species,
(T. hydatigena, T. pisiformis, T. taeniformis) Dipylidium caninum (adult and immature forms).

5. CONTRAINDICATIONS

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.
Do not use in animals with a known sensitivity to the active ingredients or to any of the excipients.

6. ADVERSE REACTIONS

None Known
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral administration.
The recommended dose rates are: 15 mg/kg bodyweight febantel, 5 mg/kg pyrantel (equivalent to 14.4 mg/kg pyrantel embonate) and 5 mg/kg praziquantel.
1 tablet per 10 kg (22 lbs) bodyweight. The tablets can be given directly to the dog or disguised in food.
No starvation is needed before, or after, treatment.

Dosage table:

Bodyweight (kg)	**Tablets**
½ - 2	1/4
3-5	½
6-10	1
11-15	1½
16-20	2
21-25	2½
26-30	3
31-35	3½
36-40	4
>40	1 tablet per 10 kg

If there is a risk for re-infestation, the advice of a veterinarian should be sought regarding the need for and the frequency of repeat administration.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure administration of a correct dose, body weight should be determined as accurately as possible
Discard any unused divided tablets.

10. WITHDRAWAL PERIOD

N/A

11. SPECIAL STORAGE PRECAUTIONS

Do not use after expiry date stated on the label.
This veterinary medicinal product does not require any special storage conditions
Keep out of the reach and sight of children.

12. SPECIAL WARNING(S)

Do not use simultaneously with piperazine compounds as the anthelmintic effects of pyrantel and piperazine may be antagonized.
Concurrent use with other cholinergic compounds can lead to toxicity.
Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.
Tapeworm infestation is unlikely in pups less than 6 weeks of age.
Teratogenic effects attributed to high doses of febantel have been reported in sheep and rats. No studies have been performed in dogs during early pregnancy. Use of the product during pregnancy should be in accordance with a benefit risk assessment by the responsible veterinarian. It is recommended that the product is not used in dogs during the first 4 weeks of pregnancy. Do not exceed the stated dose when treating pregnant bitches.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

User Precautions:
In case of accidental ingestion, seek medical advice and show the package leaflet to the physician.
In the interests of good hygiene, persons administering the tablets directly to a dog or adding them to the dog's food should wash their hands afterwards.
For animal treatment only.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused product or waste material should be disposed of in accordance with national requirements.
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 24, 28, 30, 32, 36, 40, 42, 44, 48, 50, 52, 56, 60, 70, 80, 84, 90, 98, 100, 104, 106, 120, 140, 150, 180, 200, 204, 206, 250, 280, 300, 500 and 1000 tablets.
Not all pack sizes may be marketed.