Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ZANTEL

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Per tablet

Praziquantel	50.0 mg
Fenbendazole	500.0 mg

Excipients

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

A round buff-coloured tablet with a quarter score.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

A broad spectrum anthelmintic for the treatment of mixed infections by nematodes and cestodes in dogs.

Ascarids	*Toxocara canis (immature, adult)*
	Toxascaris leonina (immature, adult)
Hookworms	*Uncinaria stenocephala (immature, adult)*
	Ancylostoma caninum (immature, adult)
Whipworms	*Trichuris vulpis (adult)*
Tapeworms	*Echinococcus granulosus*
	Echinococcus multilocularis
	Dipylidium caninum
	Taenia pisiformis
	Taenia hydatigena

4.3 Contraindications

Do not use in puppies under the age of 2 weeks.

4.4 Special warnings for each target species

Since one of the most common tapeworms of the dog and cat (*Dipylidium caninum*) is transmitted by a flea and has a very short pre-patent period, it is important to pay attention to flea control to reduce the incidence of tapeworm and the risk of re-infection.
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Refer to Section 4.3.

4.5 Special precautions for use

Special precautions for use in animals
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after the administration to the animal**.**

4.6 Adverse reactions (frequency and seriousness)

Vomiting has been reported in dogs administered the product at the recommended dose.

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats, mice and rabbits, have not produced any evidence of a teratogenic or foetotoxic effect for praziquantel and fenbendazole. The safety was not assessed in pregnant bitches. The use is not recommended during pregnancy. Safe for use in lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Zantel tablets are administered orally either directly or mixed with a portion of meat or sausage or mixed with food. Dietary measures or fasting are not necessary.
To ensure administration of a correct dose, body weight should be determined as accurately as possible.
Treatment of adult dogs and puppies from weaning
Zantel should be administered at a dose rate of 5 mg praziquantel and 50 mg fenbendazole per kg bodyweight (equivalent to 1 tablet per 10 kg) daily for 2 consecutive days.

For example :-

<u>Small dogs and weaned puppies</u>	
0.5 - 2.5 kg bodyweight	1/4 tablet
2.5 - 5 kg bodyweight	1/2 tablet
6 - 10 kg bodyweight	1 tablet
<u>Medium sized dogs</u>	
11 -15 kg bodyweight	1 1/2 tablets
16 - 20 kg bodyweight	2 tablets
21 - 25 kg bodyweight	2 1/2 tablets
26 - 30 kg bodyweight	3 tablets
<u>Large dogs</u>	
31 - 35 kg bodyweight	3 1/2 tablets
36 - 40 kg bodyweight	4 tablets

Studies have not been performed in dogs heavier than 40 kg.

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

In studies with multiple overdose administration transient diarrhoea was observed.
From 3 times the recommended dose, loose faeces in dogs and crying and restlessness in puppies were reported. At 5 times the recommended dose, excessive salivation was observed in dogs and puppies. Vomiting may also occur. Signs of overdose should be treated symptomatically.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Anthelmintic: Pharmacotherapeutic Group: Anthelmintics – Praziquantel, combinations.
ATC Vet Code: QP52AA51.

5.1 Pharmacodynamic properties

Praziquantel causes spastic paralysis of the musculature of the parasites due to a membrane depolarisation of the muscle cells. It damages the normal function of the tegument, the glucose intake from the medium is inhibited and the productic of lactate stimulated. Selective permeability of the tegument is impaired. At the molecular level the mechanism of actior that produces the tetanic paralysis is still not fully understood. Several groups have suggested that praziquantel opens calcium channels in the tegument to bring about this effect. Disintegrated and partially digested fragments of tapeworm segments may occasionally be seen in the faeces.
Fenbendazole acts against parasites by disrupting the formation of microtubules by binding to tubulin in parasitic intesti cells hence preventing the absorption of glucose, parasites are gradually starved to death. Fenbendazole displays preference for parasitic as opposed to mammalian tubulin. This appears to be due to the fact that the formation of the parasitic tubulin-fenbendazole complex is more favourable kinetically under physiological conditions than the mammali complex. Fenbendazole may also inhibit energy production in helminths by inhibition of glucose uptake and glycogen breakdown.

5.2 Pharmacokinetic properties

Following administration of Zantel tablets with food in dogs, Cmax for fenbendazole was 393 ng/ml, Tmax was 14 hour AUC was 5057 ng/ml/hr and mean half-life was 5 hours. Maximum concentrations of the active metabolite, oxfendazol were 332 ng/ml, Tmax was 16 hours, AUC was 4480 ng/ml/hr and mean half-life of elimination was 5 hours. Praziquan was rapidly absorbed C_{max} was 935 ng/ml Tmax approximately one hour, AUC was 2765 ng/ml/hr and mean half-life was 3.5 hours.

Environmental properties
Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Lauryl Sulphate,
Polyvinyl pyrrolidone (Povidone 30),
Sodium Starch Glycolate Type A,
Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
- containers: 3 years
- foil strips : 3 years
- foil blisters: 12 months
Discard part used 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

1. White high density polyethylene (HDPE) containers with a white polypropylene child resistant tamper evident cap.
2. Foil strips (LDPE/aluminium).
3. Foil blisters (aluminium/aluminium)
Pack sizes:
Containers: 20, 24, 30, 50, 60, 96, 100, 120 and 200 tablets
Foil strips and blisters: 2, 3, 4, 6, 8, 10, 12, 20, 24, 30, 48, 50, 60, 100, 120, 200 and 400 tablets
Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/060/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd November 2003
Date of last renewal: 3rd November 2008

10 DATE OF REVISION OF THE TEXT