Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Zantel Cat and Dog Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances (per tablet):

Praziquantel	50.0 mg
Fenbendazole	500.0 mg

3 PHARMACEUTICAL FORM

Tablet.
A round buff-coloured tablet with a quarter score.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats

4.2 Indications for use, specifying the target species

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

Ascarids	*Toxocara cati (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 spp.
	Mesocestoides spp

Zantel Cat and Dog tablets may also be used as an aid in the control of *Giardia* protozoa in dogs and *Aelurostrongylus abstrusus* lungworm infection in cats.

4.3 Contraindications

Do not use in kittens less than 8 weeks of age.

4.4 Special warnings for each target species

None.

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 handling tablets.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Do not exceed the stated dose when treating pregnant bitches.
A veterinary surgeon should be consulted before treating pregnant bitches for roundworm.
Do not use in pregnant cats.
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 Cat and Dog 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. Absorption may be improved with food.

Routine treatment of adult dogs
Zantel Cat and Dog should be administered as a single treatment at a dose rate of 5 mg praziquantel and 50 mg fenbendazole per kg bodyweight (equivalent to 1 tablet per 10 kg).

For example:
Small dogs and puppies over 6 months of age

0.5 - 2.5 kg bodyweight	¼ tablet
2.5 - 5 kg bodyweight	½ tablet
6 - 10 kg bodyweight	1 tablet

Medium sized dogs

11 - 15 kg bodyweight	1 ½ tablets
16 - 20 kg bodyweight	2 tablets
21 - 25kg bodyweight	2 ½ tablets
26 - 30 kg bodyweight	3 tablets

Large Dogs

31 - 35 kg bodyweight	3 ½ tablets
36 - 40 kg bodyweight	4 tablets

Routine treatment of adult cats
Zantel Cat and Dog should be administered as a single treatment at a dose rate of 5 mg praziquantel and 50 mg fenbendazole per kg bodyweight (equivalent to ½ tablet per 5kg bodyweight).

For example:

0.5 - 2.5 kg bodyweight	¼ tablet
2.5 - 5 kg bodyweight	½ tablet

For routine control adult dogs and cats should be treated once every 3 months.

Weaned puppies & kittens under 6 months of age
Zantel Cat and Dog should be administered at a dose rate of 5 mg praziquantel and 50 mg fenbendazole per kg bodyweight (equivalent to ½ tablet per 5 kg bodyweight). Treatment should be administered for three consecutive days.

Unweaned puppies and nursing bitches
For the control of *Toxocara*, it is important to worm young puppies very regularly with Zantel Cat and Dog, at a dose rate of 5 mg praziquantel and 50 mg fenbendazole per kg bodyweight daily for three consecutive days (equivalent to ½ tablet per 5 kg daily for 3 days). This treatment regimen should be repeated at 2 weekly intervals from the age of 2 weeks for pups less than 12 weeks of age. It is then recommended that Zantel Cat and Dog be administered at intervals of 3 months. Nursing bitches should be treated at the same time and as frequently as puppies up to 12 weeks of age. Thereafter the adult worming regime of once every three months is recommended.

Increased dosing for specific infections
For the treatment of *Clinical* worm infestation in adult dogs administer Zantel Cat and Dog at a dose rate of:-
5 mg praziquantel and 50 mg fenbendazole per kg bodyweight daily for two consecutive days (equivalent to 1 tablet per 10 kg daily for 2 days).

For the treatment of *Clinical* worm infestations in adult cats and as an aid in the control of the lungworm *Aelurostrongylus abstrusus* in cats and *Giardia* protozoa in dogs administer Zantel Cat and Dog at a dose rate of:-
5 mg praziquantel and 50 mg fenbendazole per kg bodyweight daily for three consecutive days (equivalent to ½ tablet per 5 kg daily for 3 days).

NOTE
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.
Praziquantel is effective against the tapeworm *Echinococcus multilocularis* in dogs and *Joyeuxiella pasqualei* in cats. These tapeworms do not occur in the UK and Ireland but are becoming more common in some European countries. As a precautionary measure it is recommended that all dogs and cats entering quarantine premises be treated with praziquantel.

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

Both fenbendazole and praziquantel are very well tolerated. After severe overdose occasional vomiting and transient diarrhoea may occur.
Inappetance may occur following high doses in cats.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QP52AA51; Pharmacotherapeutic Group: anthelmintics

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 production of lactate stimulated. The membrane is more permeable for glucose and more sensitive to the action of proteolytic enzymes.
At the molecular level the mechanism of action 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 intestinal 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 mammalian complex. Fenbendazole may also inhibit energy production in helminths by inhibition of glucose uptake and glycogen breakdown.

5.2 Pharmacokinetic properties

PRAZIQUANTEL (PRZ)
After oral administration, PRZ is very rapidly and extensively (75-100%) absorbed. Cmax is reached within 1 hour. PR rapidly enters tissues but there is no accumulation. It crosses the placenta in very small amounts, leading to very low concentrations in the foetus. About 80% of PRZ is protein bound in plasma. Serum concentration of non-metabolised praziquantel is low. There is an extensive first pass effect. Within 15 minutes of oral administration in dogs, 84% of the dose is metabolised. Plasma T ½ is about 1 hour. Most praziquantel and metabolites are eliminated via the kidneys. I dogs, < 0.3% is excreted unchanged. The remainder is excreted in bile and faeces. It is rapidly eliminated from blood a is undetectable after 24 hrs. Very small amounts are excreted in milk.

FENBENDAZOLE
Fenbendazole is poorly absorbed. Maximum plasma concentration is reached within about 20 hours and the parent drug metabolised in the liver and eliminated within 48 hours. The main metabolite, oxfendazole, also possesses anthelmintic activity. Increasing the dose rate does not significantly increase plasma levels of fenbendazole and oxfendazole.
Fenbendazole when administered with food demonstrates significantly higher bioavailability than when administered on empty stomach. Excretion is mostly in the faeces with only 10% via urine.

Following administration of Zantel tablets with food in dogs, Cmax for fenbendazole was 393 ng/ml, Tmax was 14 hou 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, Cmax was 935 ng/ml, Tmax approximately one hour, AUC was 2765 ng/ml/hr and mean half-life was 3.5 hours.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Lauryl Sulphate
Povidone 30
Sodium Starch Glycollate
Magnesium Stearate

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of veterinary medicinal product as packaged for sale: 3 years.

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. 30µ aluminium foil coated with 35 gsm extruded polythene.
3. Foil blisters (aluminium/aluminium).

Pack sizes:

Containers:	20, 24, 30, 50, 60, 96, 100 and 120 tablets.
Blisters:	2, 3, 4, 8, 10, 12, 20, 24, 30, 48, 50, 60, 100 and 120 tablets.
Strips:	2, 3, 4, 8, 10, 12, 20, 24, 30, 48, 50, 60, 100 and 120 tablets.

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 current national requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea.
Co. Galway.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/052/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4th May 2006

10 DATE OF REVISION OF THE TEXT

8th December 2009