1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zantel 50/500mg tablets for Dogs (IE, BE, CZ, EL, NO, SK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

Praziquantel	50.0 mg
Fenbendazole	500.0 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium Lauryl Sulphate
Polyvinyl pyrrolidone (Povidone 30)
Sodium Starch Glycolate Type A
Magnesium Stearate

A round buff-coloured tablet with a quarter score.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each 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

3.3 Contraindications

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

3.4 Special warnings

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 3.3

3.5 Special precautions for use

Special precautions for safe use in the target species:
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash hands after the administration to the animal.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs

Undetermined frequency	Vomiting

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative, or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
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 the whole of the pregnancy. Can be used in lactating animals.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
The veterinary medicinal product is 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 a correct dosage, body weight should be determined as accurately as possible.

Treatment of adult dogs and puppies from weaning
The veterinary medicinal product 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:-
Small dogs and weaned puppies

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	1½ tablets
16 - 20 kg bodyweight	2 tablets
21 - 25 kg bodyweight	2½ tablets
26 - 30 kg bodyweight	3 tablets

Large Dogs

31 - 35 kg bodyweight	3½ tablets
36 - 40 kg bodyweight	4 tablets

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

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal Periods

Not applicable.

4. PHARMACOLOGICAL PROPERTIES

4.1 ATC Vet Code:

QP52AA51.

4.2 Pharmacodynamics

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. Selective permeability of the tegument is impaired. 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.

4.3 Pharmacokinetics

Following administration of the veterinary medicinal product with food in dogs, Cmax for fenbendazole was 393 ng/ml, Tmax was 14 hours, AUC was 5057 ng/ml/hr and mean half-life was 5 hours. Maximum

concentrations of the active metabolite, oxfendazole were 332 ng/ml, Tmax was 16 hours, AUC was 4480 ng/ml/hr and mean half-life of elimination was 5 hours. Praziquantel 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale:
- containers: 3 years.
- foil strips: 3 years.
- foil blisters: 4 years.

Discard part used tablets.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 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, 96, 100, 120, 200 and 400 tablets.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription. NO, SK, BE, EL

Veterinary medicinal product not subject to prescription. CZ, IE,

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Container/Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zantel 50/500 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:

Praziquantel 50.0 mg

Fenbendazole 500.0 mg

3. PACKAGE SIZE

Pack sizes: 2, 3, 4, 6, 8, 10, 12, 20, 24, 30, 48, 50, 60, 96, 100, 120, 200 and 400 tablets.

4. TARGET SPECIES

Dogs.

5. INDICATION(S)

For products not subject to veterinary prescription

For the treatment of roundworms and tapeworms in dogs and puppies including:-

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* and *Taenia hydatigena* species.

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Discard part used tablets.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,

14. MARKETING AUTHORISATION NUMBER(S)

15. BATCH NUMBER

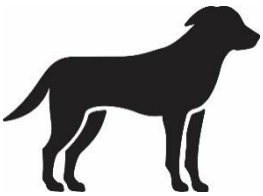
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE} Blister/Strips

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zantel



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Praziquantel	50.0 mg
Fenbendazole	500.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Discard part used tablets.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Zantel 50/500mg tablets for Dogs

2. Composition

Each tablet contains:

Active substances:

Praziquantel	50.0 mg
Fenbendazole	500.0 mg

A round buff-coloured tablet with a quarter score.

3. Target species

Dogs.

4. Indications for use

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* and *Taenia hydatigena* species.

5. Contraindications

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

6. Special warnings

Special warnings

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 'Contraindications'.

Special precautions for safe use in the target species:
None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Wash hands after the administration to the animal.

Pregnancy and lactation:

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 the whole of the pregnancy. Can be used in lactating animals.

Interaction with other medicinal products and other forms of interaction

None known.

Overdose:

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.

7. Adverse events

Dogs

Undetermined frequency	Vomiting

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes and method of administration

Oral use.

The veterinary medicinal product is 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 a correct dosage, body weight should be determined as accurately as possible.

Treatment of adult dogs and puppies from weaning

The veterinary medicinal product 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	¼ tablet
>2.5 - 5 kg bodyweight	½ tablet
6 - 10 kg bodyweight	1 tablet
<u>Medium sized dogs</u>	
11 - 15 kg bodyweight	1½ tablets
16 - 20 kg bodyweight	2 tablets
21 - 25 kg bodyweight	2½ tablets
26 - 30 kg bodyweight	3 tablets
<u>Large Dogs</u>	
31 - 35 kg bodyweight	3½ tablets
36 - 40 kg bodyweight	4 tablets

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

9. Advice on correct administration

Refer to section 'Dosage for each species, routes and method of administration'

10. Withdrawal periods

Not applicable.

11. Special storage precautions

This veterinary medicinal product does not require any special storage conditions
Keep out of the reach and sight of children.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems.
These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription. NO, SK, BE, EL

Veterinary medicinal product not subject to prescription. CZ, IE,

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

14. Marketing authorisation numbers and pack sizes

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, 96, 100, 120, 200 and 400 tablets.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:
Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway.
Ireland
Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegoup.ie

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information