Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Quanifen (50 mg Praziquantel / 500 mg Fenbendazole) Tablets for Cats and Dogs.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Tablet Contains:

Active Substances:

Praziquantel	50.0 mg
Fenbendazole	500.0 mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

A round buff-coloured tablet with a score line. The tablets can be divided into equal quarters.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

For the treatment of mixed parasitic infections in dogs and cats caused by roundworms and tapeworms of the following species:

Ascarids	*Toxocara canis* (adult)
	Toxocara cati (adult)
	Toxascaris leonina (adult)
Hookworms	*Uncinaria stenocephala* (adult)
	Ancylostoma caninum (adult)
Whipworms	*Trichuris vulpis* (adult)
Tapeworms	*Echinococcus granulosus*
	Echinococcus multilocularis
	Dipylidium caninum
	Taenia spp.
	Mesocestoides spp

4.3 Contraindications

Do not use in case of hypersensitivity to the active substances.
Do not use in kittens less than 8 weeks of age.
Do not use in pregnant cats.
Do not use in pregnant bitches up to day 39 of pregnancy.
For further information on treatment of pregnant bitches refer to section 4.7 (Use during pregnancy, lactation or lay).

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.

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

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease in the OIE, specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.
Wash hands after handling tablets.

4.6 Adverse reactions (frequency and seriousness)

Treated animals may occasionally develop vomiting or mild diarrhoea in connection with the deworming.

4.7 Use during pregnancy, lactation or lay

Do not exceed the stated dose when treating pregnant bitches. Do not use in pregnant bitches up to Day 39 of pregnancy. The product can be used for the treatment of pregnant bitches during the last third of pregnancy. However, as teratogenic effects caused by the fenbendazole metabolite oxfendazole cannot be ruled out entirely in rare cases, use only according to the benefit/risk assessment by the responsible veterinarian.
Do not use in pregnant cats.
The product can be used in lactating bitches and queens.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Administer orally either directly or mixed with food. Dietary measures or fasting are not necessary.

Dogs and cats: Single administration of this product at a dose of 5 mg praziquantel and 50 mg fenbendazole/kg bodyweight, equivalent to 1 tablet per 10 kg.
For elimination of round worm infections, the treatment needs to be continued with an appropriate veterinary medicinal product containing fenbendazole at a dose rate of 50 mg/kg bw per day for two further consecutive days.

Dosing examples:-

<u>Small dogs and puppies over 6 months of age</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

Particularly under conditions of heavy challenge, the elimination of ascarids especially in puppies and kittens can be incomplete in individual animals so that a potential risk of infection to humans remains. A re-examination should therefore be conducted and on the basis of the results a re-treatment given if necessary, according to the judgement of the veterinarian.

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. At 5 times the recommended dose, inappetance was observed in cats.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, quinoline derivatives and related substances; 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 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. Praziquantel is rapidly absorbed and metabolised by the liver. It is rapidly excreted entirely as metabolites in the urine and bile. 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. PRZ 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. In dogs, <0.3% is excreted unchanged. The remainder is excreted in bile and faeces. It is rapidly eliminated from blood and 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 is 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 an empty stomach. Excretion is mostly in the faeces with only 10% via urine.

Following administration of this product with food in dogs, mean Cmax for fenbendazole was 393 ng/ml, mean Tmax was 14 hours, mean AUC was 5057 ng/ml/hr and mean half-life was 5 hours. Mean Cmax of the active metabolite, oxfendazole was 332 ng/ml, mean Tmax was 16 hours, mean AUC was 4480 ng/ml/hr and mean half-life of elimination was 5 hours. Praziquantel was rapidly absorbed, mean Cmax was 935 ng/ml, mean Tmax approximately one hour, mean AUC was 2765 ng/ml/hr and mean half-life was 3.5 hours.

Absorption of the tablets may be improved with food.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium laurilsulfate
Povidone 30
Sodium Starch Glycolate
Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

Shelf-life of the 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

White high density polyethylene (HDPE) containers with a white polypropylene child resistant tamper evident cap.
Strips: 30 µ aluminium foil coated with 35 gsm extruded polythene.
Blisters: Foil blisters (aluminium/aluminium)

Pack sizes:

Containers:	20, 24, 30, 50, 60, 96, 100 and 120 tablets
Strips and blisters:	2, 3, 4, 8, 10, 12, 20, 24, 30, 48, 50, 60, 100 and 120 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 veterinary medicinal product or waste materials derived from the use of such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.
Loughrea
Co. Galway
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10987/063/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd April 2005
Date of last renewal: 18th October 2010

10 DATE OF REVISION OF THE TEXT