1. NAME OF THE VETERINARY MEDICINAL PRODUCT:

Quenazole (50mg praziquantel / 500mg Fenbendazole) Tablets for Cats and Dogs

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 laurilsulfate
Povidone 30
Sodium Starch Glycolate
Magnesium Stearate

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

3. CLINICAL INFORMATION:

3.1 Target Species:

Dogs and cats.

3.2 Indications for use:

For the treatment of mixed infections of roundworms and tapeworms in dogs and cats.

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

This veterinary medicinal product may also be used as an aid in the control of Giardia protozoa in dogs and *Aelurostrongylus abstrusus* lungworm infection in cats.

3.3 Contraindications:

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

Do not use in puppies under the age of 2 weeks or under 0.5 kg in weight.

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.

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 handling tablets.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

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 authorization 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:

Do not exceed the stated dose when treating pregnant bitches. Do not use in pregnant bitches before day 39 of pregnancy. This veterinary medicinal product can be used for the treatment of pregnant bitches during the last third of pregnancy. A veterinary surgeon should be consulted before treating pregnant bitches for roundworm.

Do not use in pregnant cats.

Can be used in lactating animals.

3.8 Interaction with other veterinary medicinal products and other forms of interaction:

None known.

3.9 Administration routes and dosage:

Oral use.

Administer orally either directly or mixed with food. Dietary measures or fasting are not necessary. Absorption may be improved with food.

Weaned puppies & kittens under 6 months of age:

This veterinary medicinal product 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.

Nursing bitches

This veterinary medicinal product should be administered 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). Because of the zoonotic potential of Toxocara very regular re-treatment of puppies and nursing bitches to control this parasite may be necessary. Veterinary advice should be sought before re-treatment of puppies and nursing bitches for the control of Toxocara.

Adult dogs and cats

For the treatment of worm infestations in adult dogs administer this veterinary medicinal product 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 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 this veterinary medicinal product 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).

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

Both fenbendazole and praziquantel are very well tolerated. 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, inappetence was observed in cats.

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 period:

Not applicable.

4. PHARMACOLOGICAL PROPERTIES:

4.1 ATCvet 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. 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.

4.3 Pharmacokinetics

PRAZIQUANTEL (PRZ)

After oral administration, PRZ is extensively (75-100%) absorbed. It 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. Most praziquantel and metabolites are eliminated via the kidneys. In dogs < 0.3% is excreted unchanged. The reminder is extracted in bile and faeces. It is rapidly eliminated from blood and is undetectable after 24h. Very small amounts are extracted in milk.

FENBENDAZOLE

Fenbendazole is poorly absorbed. The parent drug is metabolized 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 veterinary medicinal product with food in dogs, C_{max} for fenbendazole was 393 ng/ml, T_{max} was 14 hours, AUC was 5057 ng/mUhr and mean half-life was 5 hours. Maximum concentrations of the active metabolite, oxfendazole were 332 ng/ml, T_{max} was 16 hours, AUC was 4480 ng/mUhr and mean half-life of elimination was 5 hours. Praziquantel was rapidly absorbed, C_{max} was 935 ng/ml, T_{max} 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:3 years.

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:

Containers: 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, 96, 100 and 120 tablets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products:

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. (IS, PT)

Veterinary medicinal product not subject to prescription. (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

{NATURE/TYPE} Label & Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quenazole (50mg Praziquantel / 500mg Fenbendazole) Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains

Praziquantel 50 mg and Fenbendazole 500 mg

3. PACKAGE SIZE

Containers: 20, 24, 30, 50, 60, 96, 100 and 120 tablets.

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

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

4. TARGET SPECIES

Cats and dogs.

5. INDICATION(S)

For products not subject to veterinary prescription

For the treatment of mixed infections of roundworms and tapeworms in dogs and cats.

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

This veterinary medicinal product may also be used as an aid in the control of Giardia protozoa in dogs and *Aelurostrongylus abstrusus* lungworm infection in cats.

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIOD

8. EXPIRY DATE

Exp {mm/yyyy}

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

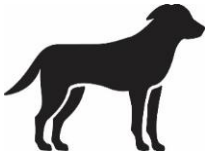
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Blisters}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quenazole



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Praziquantel 50 mg and Fenbendazole 500 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each tablet contains
Praziquantel 50 mg, Fenbendazole 500 mg

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

3. Target species

Cats & dogs.

4. Indications for use

For the treatment of mixed infections of roundworms and tapeworms in dogs and cats including:-

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

This veterinary medicinal product may also be used as an aid in the control of Giardia protozoa in dogs, and *Aelurostrongylus abstrusus* lungworm infection in cats.

5. Contraindications

Do not use in kittens less than 8 weeks of age.
Do not use in puppies under the age of 2 weeks or under 0.5 kg in weight.

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.

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 handling tablets.

Pregnancy and lactation:
Do not exceed the stated dose when treating pregnant bitches. Do not use in pregnant bitches before day 39 of pregnancy. This veterinary medicinal product can be used for the treatment of pregnant bitches during the last third of pregnancy. A veterinary surgeon should be consulted before treating pregnant bitches for roundworm.
Do not use in pregnant cats.
Can be used in lactating animals.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:

Both fenbendazole and praziquantel are very well tolerated. 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, inappetence was observed in cats.

7. Adverse events

None known.
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: Website: www.hpra.ie

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

Oral use.

Weaned puppies & kittens under 6 months of age
This veterinary medicinal product should be administered at a dose rate of 5 mg praziquantel and 50 mg fenbendazole per kg bodyweight (equivalent to $^1/_2$ tablet per 5 kg bodyweight).

Treatment should be administered for three consecutive days.

Nursing bitches

This veterinary medicinal product should be administered at a dose rate of 5 mg praziquantel and 50 mg fenbendazole per kg bodyweight daily for three consecutive days (equivalent to $^{1}/_{2}$ tablet per 5 kg daily for 3 days. Because of the zoonotic potential of Toxocara very regular re-treatment of puppies and nursing bitches to control this parasite may be necessary. Veterinary advice should be sought before re-treatment of puppies and nursing bitches for the control of Toxocara.

Adult dogs and cats

For the treatment of worm infestations in adult dogs administer this veterinary medicinal product 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 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 this veterinary medicinal product at a dose rate of 5 mg praziquantel and 50 mg fenbendazole per kg bodyweight, daily for three consecutive days, (equivalent to $^{1}/_{2}$ tablet per 5 kg daily for 3 days).

9. Advice on correct administration

Administer orally either directly or mixed with food. Dietary measures or fasting are not necessary.
Absorption may be improved with food.

10. Withdrawal periods

Not Applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

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. (IS, PT)
Veterinary medicinal product not subject to prescription. (IE)

14. Marketing authorisation numbers and pack sizes

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, 96, 100 and 120 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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

Chanelle Pharmaceuticals Manufacturing Limited.
Loughrea,
Co. Galway,
Ireland.
Telephone: +353 (0)91 841788
vetpharmacoviggroup@chanellegroup.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.