

1. NAME OF THE VETERINARY MEDICINAL PRODUCT:

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Per tablet

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:

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 product 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.

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

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

Wash hands after handling tablets

4.6 Adverse Effects (frequency and seriousness):

None known.

4.7 Use during 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 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.

Safe for use in lactating animals.

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

None known

4.9 Amounts to be Administered and method of administration:

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 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 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 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 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).

4.10 Overdose (Symptoms, Emergency Procedures, and Antidotes) (if Necessary):

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, inappetance was observed in cats.

4.11 Withdrawal period:

Not applicable.

5. PHARMACOLOGICAL PROPERTIES:

Pharmacotherapeutic group: Anthelmintic, 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 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 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. 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 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

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 contents of container:

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.

6.6 Special precautions for the disposal of unused product or waste materials, if any:

Any unused veterinary medicinal product or waste material 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)

VPA10987/062/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22/04/2005

10. Date of Revision of SPC

November / 2010

<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{NATURE/TYPE} Label & Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains Praziquantel 50 mg and Fenbendazole 500 mg

3. PHARMACEUTICAL FORM

Tablet

4. 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

5. TARGET SPECIES

Cats and Dogs.

6. INDICATION(S)

For the control of Roundworms, Tapeworms, Hookworms and Whipworms

For the oral treatment of roundworms and tapeworms including *Toxocara* species, *Toxascaris leonina*, *Uncinaria stenocephala*, *Ancylostoma caninum*, *Trichuris vulpis*, *Echinococcus* species, *Dipylidium caninum*, *Taenia* species, *Mesocestoides* species.

Also indicated as an aid in the control of *Giardia* species in dogs, and *Aelurostrongylus abstrusus* lungworm in cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use

8. WITHDRAWAL PERIOD

Not Applicable.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP.

11. SPECIAL STORAGE CONDITIONS

No special storage precautions

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste material derived from the use of such veterinary medicinal product should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For Animal Treatment Only.

CAM

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VPA Holder:

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway.

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{Blisters}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceutical Manufacturing Limited

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET
Quenazole (50mg Praziquantel / 500mg Fenbendazole) Tablets for Cats and dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

VPA Holder:

Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, Co. Galway, Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Tablet for oral administration containing:- Praziquantel 50 mg, Fenbendazole 500 mg
A round buff-coloured tablet with a score line. The tablets can be divided into equal quarters.

4. INDICATION(S)

For the control of Roundworms, Tapeworms, Hookworms and Whipworms

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

Ascarids *Toxocara canis, Toxocara cati, Toxascaris leonina*

Hookworms *Uncinaria stenocephala, Ancylostoma caninum*

Whipworms *Trichuris vulpis*

Tapeworms *Echinococcus granulosus, Echinococcus multilocularis, Dipylidium caninum, Taenia spp. and Mesocestoides species.*

This 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 0.5kg in weight.

Do not administer to pregnant cats.

Do not exceed the stated dose when treating pregnant bitches.

Do not use in pregnant bitches before day 39 of pregnancy.

This 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.

6. ADVERSE REACTION

None known.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats & Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Weaned puppies & kittens under 6 months of age

This product should be administered at a dose rate of 5 mg praziquantel and 50 mg fenbendazole per kg bodyweight (equivalent to $\frac{1}{2}$ tablet per 5 kg bodyweight).

Treatment should be administered for three consecutive days.

Nursing bitches

This 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 $\frac{1}{2}$ 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 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 product at a dose rate of 5 mg praziquantel and 50 mg fenbendazole per kg bodyweight, daily for three consecutive days, (equivalent to $\frac{1}{2}$ 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 PERIOD

Not Applicable

11. SPECIAL STORAGE PRECAUTIONS

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

12. SPECIAL WARNING(S)

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.

FOR ANIMAL TREATMENT ONLY.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Wash hand after handling tablets.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste material derived from the use of such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

MM/YYYY

15. OTHER INFORMATION>

Safe for use in lactating animals

Pack sizes:

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

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

Not all pack sizes may be marketed

Legal category: Companion Animal Medicine

CAM
