

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TapeNil 20mg Spot-on Solution for cats and kittens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml pipette contains:

Active substance:

Praziquantel 20 mg

Excipient(s):

Butylhydroxytoluene (E321) 0.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear, colourless to pale amber solution

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

For the treatment of tapeworms of cats. The product is effective against mature and immature forms of *Dipylidium caninum* and *Taenia* species. The product is also effective against *Echinococcus multilocularis*.

4.3 Contraindications

Do not use on cats weighing less than 1 kg bodyweight.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

Do not allow recently treated animals to groom each other.

4.5 Special precautions for use

i) Special precautions for use in animals

Care should be taken to avoid the contents of the tube coming into contact with the eyes or mouth of the recipient animal.
For external use only.

ii) Special precautions to be taken by the person administering the medicinal product to animals

The product can be irritating to the skin and eyes.

Care should be taken to avoid the contents of the tube coming into contact with the skin, eyes and mouth, including hand-to-mouth and hand-to-eye contact.

If accidental contact with the skin or eyes occurs, wash off any skin contamination with soap and water immediately. Rinse the affected eyes thoroughly with clean, fresh water.

In the event of skin or eye contact, seek medical advice if irritation persists and show the Doctor this package.

Do not eat, drink or smoke during application.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or label to the physician.

Laboratory studies with the excipient N-methyl-2-pyrrolidone in rabbits and rats have shown evidence of teratogenic, foetotoxic, maternotoxic and reprotoxic effects. Avoid direct contact with the product and application site.

Do not stroke or groom animals until the area of application is dry (at least one hour after application).

Wash hands thoroughly after use.

Keep product in the outer carton until ready to use.

Store away from food, drink and animal feeding stuffs.

Other precautions

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority (e. g. experts or institutes of parasitology). If the cat has visited areas where *Echinococcus* spp. are prevalent, a veterinarian should be consulted.

Keep recently treated pets away from varnished, polished, plastic or leather surfaces.

4.6 Adverse reactions (frequency and seriousness)

On very rare occasions a transient local reaction such as scurf (flaking skin) or mild exudation (weeping) may be observed at the application site following treatment.

On very rare occasions salivation may occur if the cat licks the application site immediately after treatment, as the product is bitter tasting. This is not a sign of intoxication and disappears after a short time without treatment.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

There are no contra-indications against use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No incompatibility has been observed between this product at the recommended dose and a range of common veterinary treatments.

4.9 Amount(s) to be administered and administration route

Dosage and Treatment Schedule

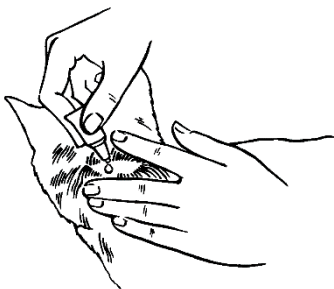
The minimum dose rate is 8 mg/kg bodyweight, which equates to 1 tube per 2.5 kg bodyweight.

Bodyweight	Number of Tubes	Quantity of Praziquantel	mg/kg bw
1 - 2.5 kg	1	20 mg	8 - 20
>2.5 - 5 kg	2	40 mg	8 - 16
>5 kg	3	60 mg	maximum 12

Method of Administration

Remove one tube from the package. Hold tube in an upright position. Tap the narrow part of the tube to ensure the contents are within the main body of the tube. Twist and pull the snap-off top of the tube to enable the contents to be expelled.

Part the hair on the cat's neck at the base of the skull until the skin is visible.



Place the tip of the tube on the skin and squeeze firmly several times to empty the contents directly onto the skin. Application at the base of the skull will minimise the opportunity for the cat to lick the product.

To minimise the possibility of run-off after application of more than one pipette, it is advised that the applications should be performed slowly to allow absorption and that it may be advisable to allow the contents of the previous pipette to be absorbed before applying another.

Tapeworm infestation is certain to re-occur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

Flea control: flea infestations can be controlled by the regular use of effective flea control remedies.

Mice control: if cats roam and hunt, contact with, and consumption of, mice and subsequent re-infestation with *Taenia taeniaeformis* is impossible to prevent.

It is recommended to re-apply the product when signs of tapeworm infestation re-appear or at monthly intervals.

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

Overdosing can lead to slight skin reactions which disappear without treatment within a few days.

4.11 Withdrawal period(s)

Not applicable as the product is not indicated for the treatment of food producing animals.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintics, Quinoline derivatives and related substances

ATCvet code: QP52AA01

5.1 Pharmacodynamics

Praziquantel is effective against all stages of development of intestinal tapeworms. The substance is very rapidly absorbed and distributed throughout the parasite. Both *in vivo* and *in vitro* studies have shown that praziquantel causes severe damage to the parasite integument, resulting in contraction and paralysis. There is an almost instantaneous tetanic contraction of the parasite musculature and a rapid vacuolisation of the syncytial tegument. This rapid contraction has been explained by changes in divalent cation fluxes, particularly calcium.

5.2 Pharmacokinetics

Praziquantel is absorbed very rapidly and almost completely in the stomach and small intestine. Studies of the behaviour following oral administration have been conducted in rats, dogs, monkeys, sheep and humans. Depending on species, maximum serum levels are reached within 0.3 to 2

hours. The chemical is evenly distributed to all organs. The elimination half-lives of ¹⁴C-praziquantel and its metabolites are between 2 and 3 hours in rats, dogs, monkeys and sheep.

Praziquantel is rapidly metabolised in the liver in both humans and animals with the 4-hydroxycyclohexyl derivative as the main metabolite. Praziquantel is completely eliminated from the body within 48 hours; irreversible binding to body constituents has not been observed. Elimination is in the form of metabolites with virtually no parent compound excreted. Between 40% and 71% of the substance is eliminated in the urine and 13%-30% in the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene E321
N-methylpyrrolidone

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place in the original package.
Store away from food, drink and animal feeding stuffs.

6.5 Nature and composition of immediate packaging

A white pipette composed of a heat-formed shell composed of polypropylene/cyclic olefin copolymer/ethylene vinyl alcohol/polypropylene layer.

Carton containing 1, 2, 3, 4 or 6 pipettes in individual foil sachets.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products 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

Vm 08749/4050

9. DATE OF FIRST AUTHORISATION

14 July 2015

10. DATE OF REVISION OF THE TEXT

June 2020

Approved 11 June 2020

