

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Droncit Spot-on 20 mg Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml pipette contains:

Active substance:

Praziquantel 20 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Butylated hydroxytoluene	0.5 mg
N-methylpyrrolidone	497.8 mg

Clear colourless to slightly reddish liquid

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in cats weighing less than 1 kg bodyweight.

3.4 Special warnings

Do not allow recently treated animals to groom each other.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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

For external use only.

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

Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. The veterinary medicinal product should not be administered by pregnant women and women suspected of being pregnant.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product by women of childbearing age.

This veterinary medicinal product can be an irritant to the skin and eyes.

Care should be taken to prevent contact of the solution with the skin or eyes.

In case of accidental spillage onto skin, wash off any skin contamination with soap and water immediately.

If accidental contact occurs with the eyes, flush the affected eyes thoroughly with clean fresh water.

In case of accidental contact with the eyes or skin, seek medical advice and if irritation persists show the package leaflet or the label to the physician.

Do not stroke or groom animals until area of application is dry (typically around 1 hour after application).

Wash hands thoroughly after use.

Do not eat, drink or smoke during application.

Store away from food, drink or animal feeding stuffs.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reaction ¹ (e.g. dandruff ¹ , exudation ^{1,2} , hair loss ¹ , reddening ¹ , itching ¹ , scab ¹) Hypersalivation ³
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1 Transient

2 Mild

3 Due to the bitter taste of the product if the cat licks the application site immediately after treatment. This is not a sign of intoxication and disappears after a short time without treatment.

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 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

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or in animals intended for breeding.

Pregnancy and lactation:

Laboratory studies in rabbits and rats with the excipient N-methylpyrrolidone have shown evidence of foetotoxic effects.

Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Dosage and Treatment Schedule:

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid underdosing.

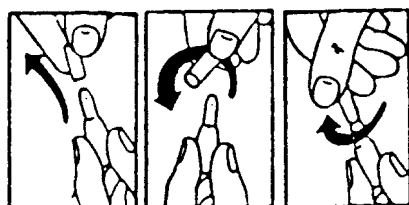
The minimum dose rate is 8 mg/kg bodyweight, which equates to 1 tube per 2.5 kg bodyweight.

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

Underdosing could result in ineffective use and may favour resistance development.

Method of Administration:

Remove one tube from the package. Hold tube in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from tube.



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 veterinary medicinal 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 veterinary medicinal product when signs of tapeworm infestation re-appear or at monthly intervals.

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

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

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 INFORMATION

4.1 ATCvet code: QP52AA01

The Active Ingredient

Praziquantel, the active ingredient of the veterinary medicinal product is a pyrazinoisoquinoline derivative used widely as an anthelmintic for both human and veterinary medicine. The chemical name for this substance is 2-cyclohexyl-carbonyl[1,2,3,6,7,11b] hexahydro-4H-pyrazino-[2,1-a]isoquinolin-4-one¹.

4.2 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.

¹ CAS number 55268-74-1

4.3 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

5.3 Special precautions for storage

Store away from food, drink and animal feeding stuffs.

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

5.4 Nature and composition of immediate packaging

White polypropylene pipettes with caps in aluminium blisters.
Blister packs in a cardboard box containing 4 unit dose pipettes (0.5 ml in each pipette).

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

Medicines should not be disposed of via wastewater.

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

Vetoquinol UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 08007/5026

8. DATE OF FIRST AUTHORISATION

21 August 2000.

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

June 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product not subject to prescription.

Find more product information by searching for the 'Product Information
Database' on www.gov.uk.

Gavin Hall

Approved: 12 June 2026