SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

WORMclear Praziquantel 20 mg Spot-on Solution for Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 pipette of 0.5 ml contains:

Active substance

Praziquantel	20.0 mg

Excipients

Butylhydroxytoluene (E321)	0.5 mg
N-methylpyrrolidone	497.8 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear, colourless to slightly reddish liquid.

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 user or the recipient animal.
Do not use if your cat is sick or recovering from illness.

For external use only.

ii) 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 product can be irritant to the skin and eyes.
Care should be taken to prevent contact of the solution with the skin or eyes.
If contact with the skin occurs, 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 the event of skin or eye contact, seek medical advice if irritation persists and show the doctor this package.
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 feedingstuffs.

4.6 Adverse events (frequency and seriousness)

Cats and kittens
Occasionally a transient local reaction, such as scurf, mild exudation, alopecia (hair loss), scab, erythema (reddening) and pruritus (itching) may be observed at the application site following treatment.

The product is bitter tasting and salivation may occasionally occur 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.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established in cats during pregnancy, lactation or in animals intended for breeding. Laboratory studies in rabbits and rats with the excipient N-methyl pyrrolidone have shown evidence of foetotoxic effects. Use only according to the benefit-risk assessment by the responsible veterinarian.

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 Amounts 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

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 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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintic: Quinoline derivatives and related substances.

ATCvet code: QP52AA01

5.1 Pharmacodynamic properties

Praziquantel, the active ingredient, 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[1,2,3,6,7,11*b*] hexahydro-4H-pyrazino-[2,1-*a*]isoquinolin-4-one[1].

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 Pharmacokinetic particulars

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 ^{14}C-

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: 30 months.

6.4 Special precautions for storage

Store away from food, drink and animal feedingstuffs.

6.5 Nature and composition of immediate packaging

White opaque polypropylene tube with an integral nozzle and rupturable membrane.
White polypropylene cap.

Blister pack of 2 or 4 unit dose tubes each containing 0.5 ml solution

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

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

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester

Northamptonshire
NN12 7LS

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4175

9. DATE OF FIRST AUTHORISATION

25 September 2014

10. DATE OF REVISION OF THE TEXT

September 2024

Gavin Hall
Approved: 25 February 2025