SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bob Martin Clear Wormer 20 mg 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

This product can be irritant to the skin and eyes.
Care should be taken to prevent contact of the solution with the skin, eyes and mouth, including hand-to eye and hand-to mouth contact.
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.
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 area of application is dry (at least 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.

iii) 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 occasionally 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

1. Hold the pipette upright and snap off the top section to open the pipette.

2. Part the coat on the back of the neck immediately behind the head until the skin is visible. If the cat is wearing a collar remove it first so that it does not restrict

application. Correct application will minimise the chance for your cat to lick the product.

3. Tap the narrow part of the pipette to ensure the contents are within the application nozzle. Place the tip of the pipette on the skin and slowly squeeze the entire contents onto the skin. Each application will be absorbed into the skin.

Allow the contents of each pipette to be absorbed before applying any additional pipettes.

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 reappear 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:
Thermoformed pipette: 2 years
Polypropylene pipette: 18 months

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Thermoformed pipettes
Violet thermoformed single-dose tubes containing an extractable volume of 0.5 ml comprising an aluminium lidded foil (polypropylene / aluminium / PET) and a laminate film (polyethylene / ethylene vinyl alcohol / polyethylene / polypropylene / cyclicolefin-copolymer / polypropylene).
The tubes are packaged in a clear PVC/PVDC/APET blister closed by heat sealing with aluminium foil and placed in a carton box or blister card.

Polypropylene pipettes
White polypropylene tube with a snap-off tab.
Blister pack of 2 or 4 unit dose tubes in a carton.

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

Pets Choice Limited
Brentwood House
Lower Philips Road
Whitebirk Industrial Estate
Blackburn
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BB1 5UD
United Kingdom

8. MARKETING AUTHORISATION NUMBER

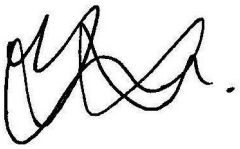
Vm 52797/4019

9. DATE OF FIRST AUTHORISATION

01 April 2015

10. DATE OF REVISION OF THE TEXT

August 2023



Approved: 09 August 2023