SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dronspot 30 mg/7.5 mg spot-on solution for small cats [BE, CZ, HU, IT, LU, NL, PL, SK, UK]

Dronspot vet 30 mg/7.5 mg spot-on solution for small cats [FI, SE]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.35 ml pipette contains:

Active substances:
Praziquantel 30 mg
Emodepside 7.5 mg

Excipients:
Butylhydroxyanisole (E320) 1.89 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear yellow to brown solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

For the treatment of mixed parasitic infections in cats caused by roundworms and tapeworms of the following species:

Roundworms (Nematodes)
Toxocara cati (mature adult, immature adult, larval stages L4 and L3)
Toxocara cati (larval stage L3) – treatment of queens during late pregnancy to prevent lactogenic transmission to the offspring
Toxascaris leonina (mature adult, immature adult and larval stage L4)
Ancylostoma tubaeforme (mature adult, immature adult and larval stage L4)

Tapeworms (Cestodes)
Dipylidium caninum (mature adult and immature adult)
Taenia taeniaeformis (adult)

Echinococcus multilocularis (adult)

4.3 Contraindications

Do not use in kittens under 8 weeks of age or weighing less than 0.5 kg.
Do not use in known cases of hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings for each target species

Shampooing or immersion of the animal in water directly after treatment may reduce the efficacy of the product. Treated animals therefore should not be bathed until the solution has dried.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

4.5 Special precautions for use

Special precautions for use in animals

Apply only to the skin surface and on intact skin. Do not administer orally or parenterally.

Avoid the treated cat or other cats in the household licking the site of application while it is wet.

There is limited experience on the use of the product in sick and debilitated animals. Therefore the product should not be administered to these animals.

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

Read the package leaflet before use.
Do not smoke, eat or drink during application.
Avoid direct contact with application area while it is wet. Keep children away from treated animals during that time.
Wash hands after use.
In case of accidental spillage onto skin, wash off immediately with soap and water.
If the product accidentally gets into eyes, they should be thoroughly flushed with plenty of water.
If skin or eye symptoms persist, or in case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Care should be taken not to allow children to have prolonged intensive contact (for example, by sleeping) with treated cats during the first 24 hours after application of the product.

The solvent in this product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the OIE, specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

4.6 Adverse reactions (frequency and seriousness)

Salivation (drooling) and vomiting may occur in very rare cases. Mild and transient neurological disorders such as ataxia (unsteady or stumbling gait) or tremor may occur in very rare cases. These effects are thought to occur as a result of the cat licking the application site immediately after treatment. In very rare cases following administration of the product transient alopecia (hair loss), pruritus (itchiness) and/or inflammation were observed at the application site.

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 or lactation

Can be used during pregnancy and lactation. See section 4.9.

4.8 Interaction with other medicinal products and other forms of interaction

Emodepside is a substrate for P-glycoprotein. Co-treatment with other drugs that are P-glycoprotein substrates/inhibitors (for example, ivermectin and other antiparasitic macrocyclic lactones, erythromycin, prednisolone and cyclosporine) could give rise to pharmacokinetic drug interactions. The potential clinical consequences of such interactions have not been investigated. If your cat is receiving any medications, please contact your vet to discuss this before applying the product. Similarly, please inform your vet that you are using this product if s/he provides your cat with any medication.

4.9 Amounts to be administered and administration route

Dosage and Treatment Schedule

The recommended minimum doses are 3 mg emodepside / kg body weight and 12 mg praziquantel / kg body weight, equivalent to 0.14 ml Dronspot / kg body weight.

Body Weight of Cat (kg)	Pipette size to be used	Volume (ml)	Emodepside (mg/kg bw)	Praziquantel (mg/kg bw)
≥0.5 - 2.5	Dronspot for Small Cats	0.35 (1 pipette)	3 - 15	12 - 60
Cats weighing over 2.5 kg bodyweight: use the appropriate Dronspot spot-on solution for cats				

For the treatment of roundworms and tapeworms a single administration per treatment is effective.

For the treatment of queens to prevent transmission of *Toxocara cati* (L_3 larval stage) through the milk to the offspring, a single administration per treatment approximately seven days prior to expected birthing is effective.

Method of administration

Spot-on use for external application to the skin.

The cat should be accurately weighed prior to treatment to ensure that the correct pipette size is used.

Remove one pipette from package. Hold pipette in upright position, twist and pull off cap and use the opposite end of the cap to break the seal.

Part the fur on the cat's neck at the base of the skull until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin. Application on the base of the skull will minimise the ability of the cat to lick the product off.

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

Salivation, vomiting and neurological signs (tremor) were observed occasionally when the product was administered at up to 10 times the recommended dose in adult cats and up to 5 times the recommended dose in kittens. These symptoms were thought to occur as a result of the cat licking the application site. The symptoms were completely reversible.
There is no known specific antidote.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: therapeutic antiparasitic agent.
ATCvet code: QP52AA51.

5.1 Pharmacodynamic properties

Emodepside is a semi-synthetic compound belonging to the new chemical group of depsipeptides. It is active against roundworms (ascarids and hookworms). In this product, emodepside is responsible for the efficacy against *Toxocara cati*, *Toxascaris leonine* and *Ancylostoma tubaeforme*.
It acts at the neuromuscular junction by stimulating presynaptic receptors belonging to the secretin receptor family which results in paralysis and death of the parasites.

Praziquantel is a pyrazinoisoquinoline derivative effective against tapeworms such as *Dipylidium caninum*, *Echinococcus multilocularis*, and *Taenia taeniaeformis*.

Praziquantel is rapidly adsorbed via the surface of the parasites and acts primarily by changing the Ca^{++} permeability of the parasite membranes. This results in severe damage to the parasite integument, contraction and paralysis, disruption of metabolism and finally leads to the death of the parasite.

5.2 Pharmacokinetic particulars

After topical application of this product to cats at the minimum therapeutic dose of 0.14 ml/kg bodyweight, mean maximum serum concentrations of 32.2 ± 23.9 µg emodepside/l and 61.3 ± 44.1 µg praziquantel/l were observed. Maximum concentrations were reached for emodepside 3.2 ± 2.7 days after application and 18.7 ± 47 hours for praziquantel. Both active substances are then slowly eliminated from the serum with a half-life of 9.2 ± 3.9 days for emodepside and 4.1 ± 1.5 days for praziquantel.
After oral application in the rat, emodepside is distributed to all organs. Highest concentration levels are found in the fat. Faecal excretion predominates with unchanged emodepside and hydroxylated derivatives as the major excretion products.
Studies in many different species show that praziquantel is rapidly metabolised in the liver. The main metabolites are monohydroxycyclohexyl derivatives of praziquantel. Renal elimination predominates.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)
1.2-Isopropylidene glycerol
Lactic acid

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Store in the original package in order to protect from moisture.
Store below 25°C.

6.5 Nature and composition of immediate packaging

White polypropylene pipettes with caps in aluminium blisters.

Pack sizes: 0.35 ml per pipette.
Blister packs containing 1, 2 or 20 unit dose pipettes.

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

The veterinary medicinal product should not be allowed to enter water courses as emodepside has shown harmful effects on aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
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Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4159

9. DATE OF FIRST AUTHORISATION

05 July 2017

10. DATE OF REVISION OF THE TEXT

November 2020

Approved 05 November 2020