

Vetoquinol UK Ltd

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Dronspot Spot-on Solution

Species:	Cats
Therapeutic indication:	Pharmaceuticals: Endoparasiticides: Anthelmintics for cats, Tapeworm products
Active ingredient:	Emodepside, Praziquantel
Product:	Dronspot® 30 mg/7.5 mg spot-on solution for small cats Dronspot® 60 mg/15 mg spot-on solution for medium cats Dronspot® 96 mg/24 mg spot-on solution for large cats
Product index:	Dronspot Spot-on Solution
Incorporating:	Dronspot Spot-on Solution for small cats Dronspot Spot-on Solution for medium cats Dronspot Spot-on Solution for large cats

Presentation

Dronspot spot-on solution for cats is a clear yellow to brown solution. The product is presented in a single use plastic pipette for dermal (spot-on) application.

Dronspot spot-on solution for small cats is a 0.35 ml pipette containing 30 mg praziquantel and 7.5 mg emodepside with 1.89 mg Butylhydroxyanisole (E320) as excipient.

Dronspot spot-on solution for medium cats is a 0.70 ml pipette containing 60 mg praziquantel and 15 mg emodepside with 3.78 mg Butylhydroxyanisole (E320) as excipient.

Dronspot spot-on solution for large cats is a 1.12 ml pipette containing 96 mg praziquantel and 24 mg emodepside with 6.05 mg Butylhydroxyanisole (E320) as

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excipient.

Uses

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)

Dosage and administration

Dosage and Treatment Schedule

See Table 1.

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.

Table 1:

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	3 – 15	12 – 60
>2.5 – 5	Dronspot for Medium Cats	0.70	3 – 6	12 – 24
>5 – 8	Dronspot for Large Cats	1.12	3 – 4.8	12 – 19.2
>8	Use an appropriate combination of pipettes			

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

For the treatment of queens to prevent lactogenic transmission of *Toxocara cati* (L3 larval stage) to the offspring, a single administration per treatment approximately seven days prior to expected birthing is effective.

Method of administration

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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. See Figure 1.

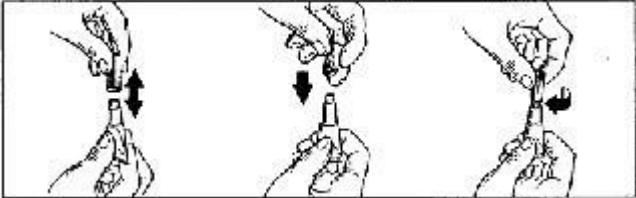


Figure 1: Opening a pipette

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. See Figure 2.

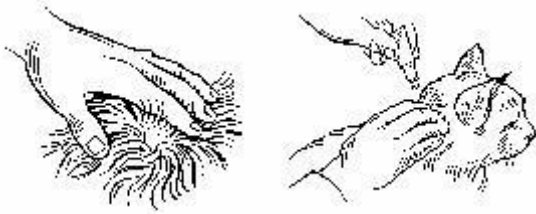


Figure 2: Administration

Use During Pregnancy or Lactation

Dronspot can be used during pregnancy and lactation.

Contra-indications, warnings, etc

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.

Special warnings

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.

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

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.

Adverse reactions

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).

Overdose

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.

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

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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.

User safety and special precautions

This product can be irritating to the skin and eyes.

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

Avoid direct contact with application area while it is wet. Keep children away from treated animals during that time.

In case of accidental contact with the skin or eyes, wash off any skin contamination immediately with soap and water.

Rinse the affected eyes thoroughly with clean, fresh water.

People with known hypersensitivity to praziquantel should avoid contact with the product.

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.

Do not smoke, eat or drink during application.

Wash hands after use.

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.

Pharmaceutical precautions

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

Store in the original package in order to protect from moisture.

Store below 25°C

Disposal

The veterinary medicinal product should not be allowed to enter water courses as emodepside has shown harmful effects on aquatic organisms.

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

These measures should help to protect the environment.

Legal category

Legal category: NFA-VPS

Packaging quantities

White polypropylene pipettes with caps in aluminium blisters. Blister packs containing 1, 2 or 20 unit dose pipettes.

Further information

Pharmacotherapeutic group: anthelmintics, quinoline derivatives and related substances; ATCvet code: QP52AA51.

Emodepside is a semi-synthetic compound belonging to the new chemical group of depsiptides. It is active against roundworms (ascarids and hookworms). In this product, emodepside is responsible for the efficacy against *Toxocara cati*, *Toxascaris leonina* 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 absorbed 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.

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.

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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.

Marketing Authorisation Holder (if different from distributor)

Marketing Authorisation Holder:

Vetoquinol UK Ltd.

Steadings Barn, Pury Hill Business Park, Towcester NN12 7LS

Marketing Authorisation Number

Dronspot 30mg/7.5mg Spot-On Small, UK: Vm 08007/4159

Dronspot 60mg/15mg Spot-On Medium, UK: Vm 08007/4160

Dronspot 96mg/24mg Spot-On Large, UK: Vm 08007/4161

Significant changes

GTIN

GTIN description:	Dronspot Spot-on Solution for Small Cats (2 Pack)
GTIN:	04007221044659
GTIN description:	Dronspot Spot-on Solution for Small Cats (20 Pack)
GTIN:	04007221044642
GTIN description:	Dronspot Spot-on Solution for Medium Cats (2 Pack)
GTIN:	04007221044635
GTIN description:	Dronspot Spot-on Solution for Medium Cats (20 Pack)
GTIN:	04007221044628
GTIN description:	Dronspot Spot-on Solution for Large Cats (2 Pack)
GTIN:	04007221044611

GTIN description: Dronspot Spot-on Solution for Large Cats (20 Pack)

GTIN: 04007221044604

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