LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Outer carton, pack size of 1 (or 2 / 20) pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dronspot 60 mg/15 mg spot-on solution for medium cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.70 ml pipette contains:
Active substances: emodepside 15 mg, praziquantel 60 mg

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZES

1 pipette
2 pipettes
20 pipettes

5. TARGET SPECIES

For medium cats > 2.5 kg – 5 kg

6. INDICATION(S)

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

Roundworms:
Toxocara cati, Toxascaris leonina, Ancylostoma tubaeforme

Tapeworms:
Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis

For the complete indication, including the larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Spot-on use for external application to the skin.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4160

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dronspot for cats (>2.5-5 kg)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

Spot-on use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dronspot spot-on solution for medium cats (>2.5-5 kg)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Lot: {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

Manufacturer responsible for batch release:
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
Germany

2. NAME OF THE VETERINARY MEDICINAL 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

Praziquantel / Emodepside

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each pipette contains:

	Active substances:		Excipient:
Unit Dose	**Emodepside**	**Praziquantel**	**Butylhydroxyanisole (E 320)**
0.35 ml	7.5 mg	30 mg	1.89 mg
0.70 ml	15 mg	60 mg	3.78 mg
1.12 ml	24 mg	96 mg	6.05 mg

Spot-on solution.
Clear yellow to brown solution.

4. INDICATIONS

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)

5. 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.

6. 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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

[to be added if nationally required]
Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Spot-on use for external application to the skin.

Dosage and Treatment Schedule

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

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.

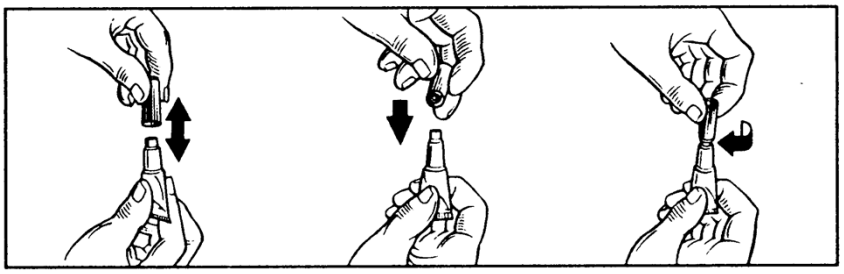
Body Weight of Cat (kg)	Pipette size to be used	Volume (ml)	Emodepside (mg/kg bw)	Praziquantel (mg/kg bw)
≥0.5 - 2.5	Dronspot for Small Cats	0.35 (1 pipette)	3 - 15	12 - 60
>2.5 - 5	Dronspot for Medium Cats	0.70 (1 pipette)	3 - 6	12 - 24
>5 - 8	Dronspot for Large Cats	1.12 (1 pipette)	3 - 4.8	12 - 19.2
>8	Use an appropriate combination of pipettes			

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

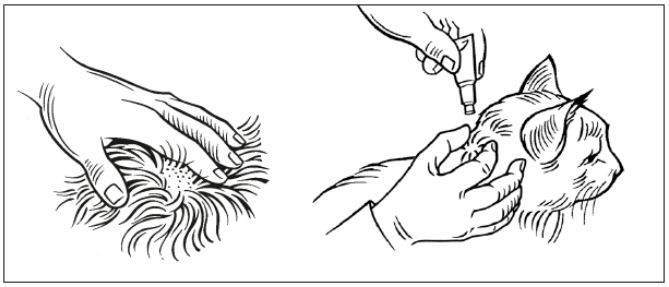
For the treatment of queens to prevent transmission of *Toxocara cati* (L_3 larval stage) through the milk to the offspring, a single administration per treatment approximately seven days prior to expected birthing is effective.

9. ADVICE ON CORRECT ADMINISTRATION

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. Apply only to the skin surface and on intact skin.



10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original package in order to protect from moisture.
Store below 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

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.

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:
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.

Pregnancy and lactation:
This veterinary medicinal product can be used during pregnancy and lactation.
See also section 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.

Overdose (symptoms, emergency procedures, antidotes):
Salivation, vomiting and trembling 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.

Incompatibilities:
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2022

15. OTHER INFORMATION

Pack sizes: 0.35 ml, 0.70 ml and 1.12 ml per pipette; blister packs containing 1, 2 or 20 unit dose pipettes.

Not all pack sizes may be marketed.

Approved 14 September 2022