ANNEX I

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, NI, NL, PL, SK,]
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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisole (E320; as antioxidant)	1.89 mg
1,2-Isopropylidene glycerol	
Lactic acid	

Clear yellow to brown solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each 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)

3.3 Contraindications

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

3.4 Special warnings

Shampooing or immersion of the animal in water directly after treatment may reduce the efficacy of the veterinary medicinal 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, repeateduse of an anthelmintic of that class.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal product in sick and debilitated animals. Therefore the veterinary medicinal product should not be administered to these animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product.
Do not smoke, eat or drink during application.
Wash hands after use.

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.

Special precautions for the protection of the environment:
Not applicable.

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

3.6 Adverse events

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Neurological disorder (e.g. ataxia (unsteady gait), tremor)[1,2,3] Hypersalivation (drooling)[3], vomiting[3], diarrhoea[3] Application site alopecia (hair loss)[2], application site pruritus (itching), application site inflammation Behavioural disorder (e.g. hyperactivity, anxiety, vocalisation) Anorexia, lethargy

[1] *Mild.*
[2] *Transient.*
[3] *These signs are thought to occur as a result of the cat licking the application site immediately after treatment.*

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation. See section 3.9.

3.8 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 veterinary medicinal product.
Similarly, please inform your vet that you are using this veterinary medicinal product before your cat receives any medication.

3.9 Administration routes and dosage

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 of the veterinary medicinal product / 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 veterinary medicinal product off.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Salivation, vomiting and neurological signs (tremor) were observed occasionally when the veterinary medicinal 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP52AA51.

4.2 Pharmacodynamics

Emodepside is a semi-synthetic compound belonging to the new chemical group of depsipeptides. It is active against roundworms (ascarids and hookworms). In this veterinary medicinal 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 theparasite.

4.3 Pharmacokinetics

After topical application of this veterinary medicinal 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 µgpraziquantel/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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

White polypropylene pipettes with caps in aluminium blisters.
Blister packs in a cardboard box containing 1, 2 or 20 unit dose pipettes (0.35 ml in each pipette).

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as emodepside may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER(S)

[*to be completed*]

8. DATE OF FIRST AUTHORISATION

[*to be completed*]

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription [IT]
Veterinary medicinal product not subject to prescription [BE] [FI] [HU] [LU] [NI] [NL] [PL] [SE] [SK]
Veterinary medicinal product subject to prescription except for some pack sizes. [CZ]

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dronspot 30 mg/7.5 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.35 ml pipette contains:
emodepside 7.5 mg, praziquantel 30 mg

3. PACKAGE SIZE

1 pipette
2 pipettes
20 pipettes

4. TARGET SPECIES

For small cats

≥ 0.5 - 2.5 kg

5. INDICATIONS

For products not subject to veterinary prescription:

Roundworms and tapeworms

For the treatment of mixed infections in cats caused by roundworms and tapeworms.

6. ROUTES OF ADMINISTRATION

Spot-on use.
For external application to the skin.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

[*to be completed*]

14. MARKETING AUTHORISATION NUMBERS

[*to be completed*]

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dronspot ≥ 0.5 - 2.5 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

7.5 mg / 30 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Vetoquinol logo

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MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dronspot ≥ 0.5–2.5 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

7.5 mg emodepside / 30 mg praziquantel

3. BATCH NUMBER

Lot: {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Vetoquinol logo

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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, NI]
Dronspot 60 mg / 15 mg spot-on solution for medium cats
Dronspot 96 mg / 24 mg spot-on solution for large cats

Dronspot vet 30 mg / 7.5 mg spot-on solution for small cats [FI, SE]
Dronspot vet 60 mg / 15 mg spot-on solution for medium cats
Dronspot vet 96 mg / 24 mg spot-on solution for large cats

2. Composition

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

Clear yellow to brown solution.

3. Target species

Cats.

4. Indications for use

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 cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

Special warnings:
Shampooing or immersion of the animal in water directly after treatment may reduce the efficacy of the veterinary medicinal 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, repeateduse of an anthelmintic of that class.

Special precautions for safe use in the target species:
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 veterinary medicinal product in sick and debilitated animals. Therefore the veterinary medicinal product should not be administered to these animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product.
Do not smoke, eat or drink during application.
Wash hands after use.

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.

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

Pregnancy and lactation:
This veterinary medicinal product can be used during pregnancy and lactation.See also section ‘Dosage for each species, routes and method of administration’.

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 veterinary medicinal product.
Similarly, please inform your vet that you are using this veterinary medicinal product before your cat

receives any medication.

Overdose:
Salivation, vomiting and trembling were observed occasionally when the veterinary medicinal 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.

Major incompatibilities:
None known.

7. Adverse events

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Neurological disorder (ataxia (unsteady gait), tremor)[1,2,3] Hypersalivation (drooling)[3], vomiting[3], diarrhoea[3] Application site alopecia (hair loss)[2], application site itching, application site inflammation Behavioural disorder (e.g. hyperactivity, anxiety, vocalisation) Anorexia, lethargy

[1] Mild
[2] Transient
[3] These signs are thought to occur as a result of the cat licking the application site immediately after treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or its local representative> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes 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 of the veterinary medicinal product / 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			

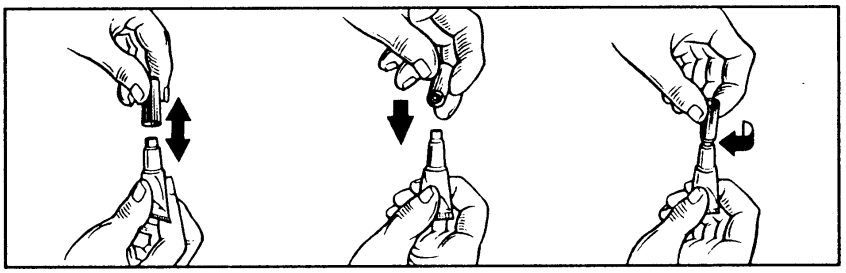
For the treatment of roundworms and tapeworms a single administration per treatment is effective.

For the treatment of queens to prevent transmission of *Toxocara cati* (L3 larval stage) through the

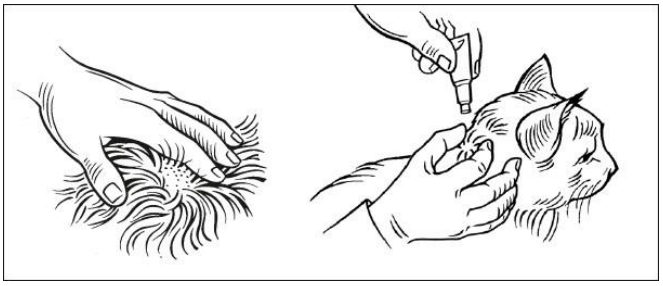
milkto the offspring, a single administration per treatment approximately seven days prior to expected birthing is effective.

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 veterinary medicinal product off. Apply only to the skin surface and on intact skin.



10. Withdrawal periods

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 after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as emodepside may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials

derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeonor pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription [IT]
Veterinary medicinal product not subject to prescription [BE] [FI] [HU] [LU] [NI] [NL] [PL] [SE] [SK]
Veterinary medicinal product subject to prescription except for some pack sizes. [CZ]

14. Marketing authorisation numbers and pack sizes

[*to be completed*]

White polypropylene pipettes with caps in aluminium blisters

Blister packs in a cardboard box containing 1,2 or 20 unit dose pipettes (0.35 ml in each pipette).
Blister packs in a cardboard box containing 1,2 or 20 unit dose pipettes (0.70 ml in each pipette).
Blister packs in a cardboard box containing 1,2 or 20 unit dose pipettes (1.12 ml in each pipette).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:

Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
Germany

VETOQUINOL BIOWET Sp. z o.o.
Żwirowa 140
66-400 Gorzów Wlkp.
Poland

Local representatives and contact details to report suspected adverse reactions:
[*to be completed*]