1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 30 mg/7.5 mg spot-on solution for small cats
Profender 60 mg/15 mg spot-on solution for medium cats
Profender 96 mg/24 mg spot-on solution for large cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Each ml contains:
21.4 mg/ml emodepside and 85.8 mg/ml praziquantel.

Each dosing unit (pipette) contains:

	Volume	**Emodepside**	**Praziquantel**
Profender for small cats (≥ 0.5 - 2.5 kg)	0.35 ml	7.5 mg	30 mg
Profender for medium cats (> 2.5 - 5 kg)	0.70 ml	15 mg	60 mg
Profender for large cats (> 5 - 8 kg)	1.12 ml	24 mg	96 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)	5.4 mg/ml
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 cats suffering from, or at risk from, mixed parasitic infections caused by roundworms, tapeworms and lungworms of the following species:

Roundworms (nematodes)
Toxocara cati (mature adult, immature adult, L4 and L3)
Toxocara cati (L3 larvae) - treatment of queens during late pregnancy to prevent lactogenic transmission to the offspring
Toxascaris leonina (mature adult, immature adult and L4)
Ancylostoma tubaeforme (mature adult, immature adult and L4)

Tapeworms (cestodes)
Dipylidium caninum (mature adult and immature adult)
Taenia taeniaeformis (adult)
Echinococcus multilocularis (adult)

Lungworms
Aelurostrongylus abstrusus (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, repeated use of an anthelmintic of that class.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with roundworms, tapeworms and lungworms should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.

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, thus the veterinary medicinal product should only be used based on a benefit-risk assessment for 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 veterinary medicinal 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 veterinary medicinal product.

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 disorders[1,2,3] (ataxia[1,2,3], tremor[1,2,3]) Hypersalivation[3], vomiting[3], diarrhoea[3] Application site alopecia[2], application site pruritus, application site inflammation Behavioural disorders (hyperactivity, anxiety, vocalisation) Anorexia, lethargy

[1] Mild
[2] Transient
[3] These effects 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.

3.8 Interaction with other medicinal products and other forms of interaction

Emodepside is a substrate for P-glycoprotein. Co-treatment with other veterinary medicinal products 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.

3.9 Administration routes and dosage

Spot-on use.
For external use only.

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 (bw).

Body weight of cat (kg)	Pipette size to be used	Volume (ml)	Emodepside (mg/kg bw)	Praziquantel (mg/kg bw)
≥ 0.5 - 2.5	Profender for small cats	0.35 (1 pipette)	3 - 15	12 - 60
> 2.5 - 5	Profender for medium cats	0.70 (1 pipette)	3 - 6	12 - 24
> 5 - 8	Profender 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 lactogenic transmission of *Toxocara cati* (L_3 larvae) to the offspring, a single administration per treatment approximately seven days prior to expected parturition is effective.

For the lungworm *Aelurostrongylus abstrusus*, two treatments administered two weeks apart are effective.

Method of 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.

Underdosing could result in ineffective use and may favour resistance development

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

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 leonina*, *Ancylostoma tubaeforme,* and *Aelurostrongylus abstrusus*.
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.

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 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.

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.

5.4 Nature and composition of immediate packaging

White polypropylene pipettes with caps in aluminium blisters

Blister packs in a cardboard box containing 2, 4, 12, 20 or 40 dose pipettes (0.35 ml each).
Blister packs in a cardboard box containing 2, 4, 12, 20, 40 or 80 dose pipettes (0.70 ml each).
Blister packs in a cardboard box containing 2, 4, 12, 20, or 40 dose pipettes (1.12 ml each).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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)

EU/2/05/054/001-016

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 27/07/2005.

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.

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