

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE – OUTER CARTON**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Profender 85.8 mg/ml + 21.4 mg/ml Multidose Spot-on Solution

### **2. STATEMENT OF ACTIVE SUBSTANCES**

21.4 mg/ml emodepside, 85.8 mg/ml praziquantel

### **3. PACKAGE SIZE**

14 ml

### **4. TARGET SPECIES**

Cats

### **5. INDICATIONS**

### **6. ROUTES OF ADMINISTRATION**

Spot-on solution

For external use only.



### **7. WITHDRAWAL PERIODS**

### **8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened, use within 3 months....

### **9. SPECIAL STORAGE PRECAUTIONS**

### **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.

**12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Vetoquinol SA

**14. MARKETING AUTHORISATION NUMBERS**

Vm 06462/5019

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS – BOTTLE LABEL**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Profender multidose spot-on solution for cats

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

21.4 mg/ml emodepside, 85.8 mg/ml praziquantel

14 ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened, use within 3 months, by.....**leave space for the date to be inserted**).

***Vetoquinol logo***

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

Profender 85.8 mg/ml + 21.4 mg/ml Multidose Spotmultidose -on Solution for Cats

**2. Composition**

**Active substances:**

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

**Excipients:**

Butylhydroxyanisole (E320; as antioxidant) 5.4 mg/ml

Clear yellow to brown solution.

**3. Target species**

Cats.

**4. Indications for use**

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)

**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, 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 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.

### 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:

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 World Organisation for Animal Health (WOAH), 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 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:

Can be used during pregnancy and lactation.

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.

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 disorders <sup>1,2,3</sup> (ataxia <sup>1,2,3</sup> (incoordination) tremor <sup>1,2,3</sup> ) Hypersalivation <sup>3</sup> , vomiting <sup>3</sup> , diarrhoea <sup>3</sup> Application site alopecia <sup>2</sup> (hair loss), application site pruritus (itching), application site inflammation Behavioural disorders (hyperactivity, anxiety, vocalisation) Anorexia, lethargy
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<sup>1</sup> Mild

<sup>2</sup> Transient

<sup>3</sup> 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 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 using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## 8. Dosage for each species, routes and method of administration

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).

Either calculate the exact dose based on the individual body weight, or use the following dose volumes recommended for the different weight ranges:

Body weight of cat (kg)	Volume (ml)	Emodepside		Praziquantel	
		(mg)	(mg/kg bw)	(mg)	(mg/kg bw)
≥0.5 - 2.5	0.35	7.5	3 - 15	30	12 - 60
>2.5 - 5	0.70	15	3 - 6	60	12 - 24
>5 - 8	1.12	24	3 - 4.8	96	12 - 19.2
>8	Appropriate combination of volumes				

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

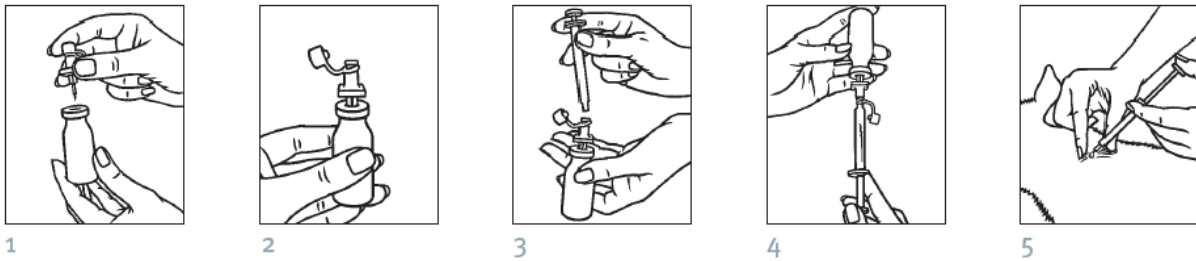
For the treatment of queens to prevent lactogenic transmission of *Toxocara cati* (L<sub>3</sub> larvae) to the offspring, a single administration per treatment approximately seven days prior to expected parturition is effective.

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

## 9. Advice on correct administration

Take the adapter, remove protective cover from the spike and insert spike into the central area of the stopper (1). Remove screw cap (2). Take a standard disposable 1 ml syringe with luer nozzle and connect it to the adapter (3). Then turn bottle up-side down and withdraw the necessary volume (4). Replace screw cap after use. Part the fur on the cat's neck at the base of the skull until the skin is visible.

Place the tip of the syringe on the skin and empty the contents directly onto the skin (5).



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. 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.

#### **10. Withdrawal periods**

Not applicable.

#### **11. Special storage precautions**

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

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.

Shelf life after first opening the immediate packaging: 3 months.

#### **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.

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 surgeon or pharmacist how to dispose of medicines no longer required.

#### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

#### **14. Marketing authorisation numbers and pack sizes**

Vm 06462/5019

Cardboard box with 1 x 14 ml bottle and a micro-spike adapter with a luer-port.

#### **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

#### **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

Vetoquinol SA  
34 Rue de Chene Sainte-Anne  
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

#### **17. Other information**

POM-V

*Gavin Hall*  
Approved: 12 January 2026