

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

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

Profender 50 mg / 10 mg modified-release tablets

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

10 mg emodepside, 50 mg praziquantel.

### **3. PACKAGE SIZE**

2 modified-release tablets  
4 modified-release tablets  
6 modified-release tablets  
24 modified-release tablets  
102 modified-release tablets

### **4. TARGET SPECIES**

Dogs.



### **5. INDICATIONS**

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

Oral use.

1 tablet = 10 kg (with bone-shaped tablet pictogram/graphic)

### **7. WITHDRAWAL PERIODS**

### **8. EXPIRY DATE**

Exp. {mm/yyyy}  
Once opened, use immediately.

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

Store in the original package in order to protect from moisture.  
Any unused half tablet should be discarded.

**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 06462/5008

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS BLISTER**

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

Profender tablets for medium dogs



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

10 mg emodepside / 50 mg praziquantel

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

*Vetoquinol logo*

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

**PACKAGE LEAFLET**

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

Profender 15 mg/3 mg modified-release tablets for small dogs  
Profender 50 mg/10 mg modified-release tablets for medium dogs  
Profender 150 mg/30 mg modified-release Tablets for large dogs

**2. Composition**

Each modified-release tablet contains:

	<b>Emodepside</b>	<b>Praziquantel</b>
Profender tablets for small dogs	3 mg	15 mg
Profender tablets for medium dogs	10 mg	50 mg
Profender tablets for large dogs	30 mg	150 mg

Brown, bone-shaped tablets with a score mark on each side.  
The tablets can be divided into equal halves.

**3. Target species**

Dogs.

**4. Indications for use**

For dogs suffering from, or at risk from, mixed parasitic infections caused by roundworms and tapeworms of the following species:

Roundworms (nematodes)

*Toxocara canis* (mature adult, immature adult, L4 and L3)  
*Toxascaris leonina* (mature adult, immature adult and L4)  
*Ancylostoma caninum* (mature adult and immature adult)  
*Uncinaria stenocephala* (mature adult and immature adult)  
*Trichuris vulpis* (mature adult, immature adult and L4)

Tapeworms (cestodes)

*Dipylidium caninum*  
*Taenia* spp.  
*Echinococcus multilocularis* (mature adult and immature)  
*Echinococcus granulosus* (mature adult and immature)

**5. Contraindications**

Do not use in puppies under 12 weeks of age or weighing less than 1 kg.

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

## **6. Special warnings**

### Special warnings:

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 and tapeworms should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.

### Special precautions for use in the target species:

Administer only to fasted dogs. For example: Overnight fasting if the dog is to be treated in the morning. No food should be given until 4 hours after treatment.

When *D. caninum* infection is present, concomitant treatment against intermediate hosts such as fleas and lice should be considered to prevent reinfection.

No studies have been performed with severely debilitated dogs or individuals with seriously compromised kidney or liver function. Therefore, the veterinary medicinal product should only be used in such animals according to a benefit/risk assessment by the responsible veterinarian.

### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In the interests of good hygiene, wash your hands after administering the tablets to the dog. In case of accidental ingestion, especially in the case of children, seek medical advice and show the package leaflet or the label to the physician.

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.

### 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 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.

Overdose:

Transient muscular tremors, incoordination and depression were occasionally observed when the veterinary product was administered at overdoses of up to 5 times the recommended dose. In *mdr1* mutant (-/-) Collies the margin of safety appears lower compared to the normal dog population, with mild transient tremor and/or ataxia occasionally observed after twice the recommended dose, in dogs fasted as recommended.

The symptoms were completely self-resolving without any treatment. Feeding can increase the frequency and intensity of such overdose symptoms and occasionally vomiting may occur.

Specific antidotes are not known.

Major incompatibilities:

Not applicable.

**7. Adverse events**

Dogs:

Very rare ( $< 1$ animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders <sup>1</sup> (e.g. hypersalivation, vomiting, diarrhoea) <sup>1</sup> Neurological disorders <sup>1,2</sup> (e.g. tremor, incoordination) <sup>1,2</sup> , Convulsion <sup>3</sup> Behavioural disorders (e.g. hyperactivity) Anorexia, lethargy, recumbency, hyperthermia.
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<sup>1</sup> Mild and transient

<sup>2</sup> Non-compliance with fasting requirements tended to be a feature of those cases

<sup>3</sup> Signs of neurological disorders may be more severe in *mdr1* mutant (-/-) Collies, Shelties and Australian Shepherds. Specific antidotes are not known

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 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**

For oral use in dogs from 12 weeks of age and weighing at least 1 kg.

The veterinary medicinal product is to be administered at a minimum dose of 1 mg/kg body weight emodepside and 5 mg/kg body weight praziquantel, according to the following dosage table.

A single administration per treatment is effective.

Body weight (kg)	Number of modified-release tablets for		
	small dogs 1  = 3 kg	medium dogs 1  = 10 kg	large dogs  = 30 kg
1 - 1.5	1/2		
> 1.5 - 3	1		
> 3 - 4.5	1 1/2		
> 4.5 - 6	2		
> 6 - 10		1	
> 10 - 15		1 1/2	
> 15 - 20		2	
> 20 - 30			1
> 30 - 45			1 1/2
> 45 - 60			2

### 9. Advice on correct administration

The veterinary medicinal product tablets are meat flavoured and usually dogs will accept them without any food.

Administer only to fasted dogs. For example: Overnight fasting if the dog is to be treated in the morning. No food should be given until 4 hours after treatment.

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.

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

Any unused half tablet should be discarded.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: use immediately.

### 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**

Profender 15 mg / 3 mg modified-release tablets for small dogs – Vm 06462/5006

Profender 50 mg / 10 mg modified-release tablets for medium dogs – Vm 06462/5008

Profender 150 mg / 30 mg modified-release tablets for large dogs – Vm 06462/5007

#### Pack sizes:

Profender 15 mg / 3 mg modified-release tablets for small dogs

- 2 tablets (1 blister strip)
- 4 tablets (1 blister strip)
- 10 tablets (1 blister strip)
- 24 tablets (3 blister strips with 8 tablets each)
- 50 tablets (5 blister strips with 10 tablets each)

Profender 50 mg / 10 mg modified-release tablets for medium dogs

- 2 tablets (1 blister strip)
- 4 tablets (1 blister strip)
- 6 tablets (1 blister strip)
- 24 tablets (4 blister strips with 6 tablets each)
- 102 tablets (17 blister strips with 6 tablets each)

Profender 150 mg / 30 mg modified-release tablets for large dogs

- 2 tablets (1 blister strip)
- 4 tablets (1 blister strip)
- 24 tablets (6 blister strips with 4 tablets each)
- 52 tablets (13 blister strips with 4 tablets each)

Not all pack sizes may be marketed.

### **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 S.A.  
Magny-Vernois  
70200 Lure  
France

### **17. Other information**

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*Gavin Hall*  
Approved: 12 January 2026