

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each modified-release tablet contains:

Active substances:

Emodepside	3 mg
Praziquantel	15 mg

Excipients:

Qualitative composition of excipients and other constituents
Calcium hydrogen phosphate anhydrous
Cellulose, microcrystalline
Silica, colloidal anhydrous
Croscarmellose sodium
Magnesium stearate
Povidone
Artificial beef flavour

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

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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)

3.3 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.

3.4 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 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 and tapeworms 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:

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 immediately 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.

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

3.6 Adverse events

Dogs:

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

² Non-compliance with fasting requirements tended to be a feature of those cases

³ 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy or lactation

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 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.

3.9 Administration routes and dosage

Dosage and treatment schedule

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	medium dogs	large dogs
	1  = 3 kg	1  = 10 kg	1  = 30 kg
1 - 1.5	½		
> 1.5 - 3	1		
> 3 - 4.5	1½		
> 4.5 - 6	2		
> 6 - 10		1	
> 10 - 15		1½	
> 15 - 20		2	
> 20 - 30			1
> 30 - 45			1½
> 45 - 60			2

Method of administration

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

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

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 incidence and intensity of such overdose symptoms and occasionally vomiting may occur.

Specific antidotes are not known.

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, hookworms and whipworms). In this veterinary medicinal product, emodepside is responsible for the efficacy against *Toxocara canis*, *Toxascaris leonina*, *Ancylostoma caninum*, *Uncinaria stenocephala* and *Trichuris vulpis*.

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*, *Taenia* spp., *Echinococcus multilocularis* and *Echinococcus granulosus*.

Praziquantel is rapidly adsorbed via the surface of the parasites and acts primarily by changing the calcium (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 treatment with a dose of 1.5 mg emodepside and 7.5 mg praziquantel per kg bodyweight, geometric mean maximum plasma concentrations of 47 µg emodepside/l and 593 µg praziquantel/l were observed. Maximum concentrations were reached 2 hours after treatment for both active substances. Both active substances were then eliminated from the plasma with a half-life of 1.4 to 1.7 hours. After oral application in the rat, emodepside is distributed to all organs. Highest concentration levels are found in the fat. Unchanged emodepside and hydroxylated derivatives are the major excretion products. The excretion of emodepside has not been investigated in dogs.

Studies in many different species show that praziquantel is rapidly metabolised in the liver. The main metabolites are monohydroxycyclohexyl derivatives of praziquantel. Renal excretion of metabolites predominates.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Cardboard boxes containing aluminium foil blister strips. The following pack sizes are available:

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

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

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

Medicines should not be disposed of via wastewater.

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 SA

7. MARKETING AUTHORISATION NUMBER

Vm 06462/5006

8. DATE OF FIRST AUTHORISATION

27 July 2005

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

October 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 12 January 2026