

Profender Spot-on Solution

Introduction



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Incorporating the data sheets for the following products:

Profender Spot-on Solution for small cats

Profender Spot-on Solution for medium cats

Profender Spot-on Solution for large cats

Presentation

Profender spot-on solution for cats is a clear yellow to brown solution containing 21.4 mg/ml emodepside and 85.8 mg/ml praziquantel, with 5.4 mg/ml butylhydroxyanisole as antioxidant. The product is presented in a single use plastic tube for dermal (spot-on) application.

Profender spot-on solution for small cats is a 0.35 ml tube containing 7.5 mg emodepside and 30 mg praziquantel.

Profender spot-on solution for medium cats is a 0.70 ml tube containing 15 mg emodepside and 60 mg praziquantel.

Profender spot-on solution for large cats is a 1.12 ml tube containing 24 mg emodepside and 96 mg praziquantel.

Uses

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

Roundworms (Nematodes)

Toxocara cati (mature adult, immature adult, L4 and L3)

Toxascaris leonina (mature adult, immature adult and L4)

Ancylostoma tubaeforme (mature adult, immature adult and L4)

Tapeworms (Cestodes)

Dipylidium caninum (adult)

Taenia taeniaeformis (adult)

Echinococcus multilocularis (adult)

Dosage and administration

Dosage and Treatment Schedule

See Table 1.

The recommended minimum doses are 3 mg emodepside/kg body weight and 12 mg praziquantel/kg body weight, equivalent to 0.14 ml Profender/kg body weight. A single administration per treatment is effective.

Table 1:

Bodyweight 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	3 - 15	12 - 60
>2.5 - 5	Profender for Medium Cats	0.70	3 - 6	12 - 24
>5 - 8	Profender for Large Cats	1.12	3 - 4.8	12 - 19.2
>8	Use an appropriate combination of pipettes			

Method of administration

For external use only.

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. See figure 1.

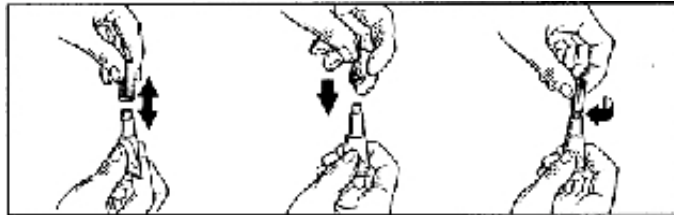


Figure 1: Opening a tube

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. See figure 2.



Figure 2: Administration

Use During Pregnancy and Lactation

Profender can be used during pregnancy and lactation.

Contra-indications, warnings, etc

Do not use in kittens under 8 weeks of age or weighing less than 0.5 kg.

Salivation and vomiting may occasionally occur. This is thought to occur as a result of the cat licking the application site immediately after treatment.

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.

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

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.

Shampooing or immersion of the animal in water directly after treatment may reduce the efficacy of the product. Treated animals therefore should not be bathed until the solution has dried.

There is limited experience on the use of the product in sick and debilitated animals, thus the product should only be used based on a benefit-risk assessment for these animals.

User Safety

Read the package insert 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 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 and show the package insert 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 product.

Frequent users of the product (for example, veterinarians, professional cat breeders) should wear disposable gloves when administering the product.

Although the product was well tolerated by pregnant cats, studies performed in rats and rabbits suggest that emodepside may interfere with embryo-foetal development. Therefore, women of child-bearing potential should avoid contact with, or wear disposable gloves when administering, the product.

Environmental Safety

Profender should not be allowed to enter surface water as emodepside has shown harmful effects on aquatic organisms.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Pharmaceutical precautions

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

Legal category

POM-V (previously POM)

Packaging Quantities

Container: white polypropylene pipettes with caps in aluminium blisters. Blister packs containing 2 or 40 unit dose pipettes.

Further information

Pharmacotherapeutic group: therapeutic antiparasitic agent; ATCvet code: QP52AA51.

Emodepside is a semi-synthetic compound belonging to the new chemical group of depsipeptides. It is active against roundworms (ascarids and hookworms). In this product, emodepside is responsible for the efficacy against *Toxocara cati*, *Toxascaris leonina*, 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 the parasite.

After topical application of this 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.

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

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.

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.

Marketing authorisation number

<i>Product</i>	<i>Pack size</i>	<i>MA Number</i>
Profender spot-on solution for small cats	2 pipettes	EU/2/05/054/001
Profender spot-on solution for small cats	40 pipettes	EU/2/05/054/005
Profender spot-on solution for medium cats	2 pipettes	EU/2/05/054/006
Profender spot-on solution for medium cats	40 pipettes	EU/2/05/054/010
Profender spot-on solution for large cats	2 pipettes	EU/2/05/054/012
Profender spot-on solution for large cats	40 pipettes	EU/2/05/054/016

Marketing Authorisation Holder

Bayer Healthcare AG, D-51368 Leverkusen, Germany

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