ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

[Single-dose pipettes]

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:

Profender contains 21.4 mg/ml emodepside and 85.8 mg/ml praziquantel.

Each unit dose (pipette) of Profender 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:

5.4 mg/ml butylhydroxyanisole (E320; as antioxidant)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear yellow to brown solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the 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)

4.3 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.

4.4 Special warnings for each target species

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.

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

4.5 Special precautions for use

Special precautions for use in animals

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 product in sick and debilitated animals, thus the 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 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 product.

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.

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.

4.6 Adverse reactions (frequency and seriousness)

Salivation and vomiting may occur in very rare cases. Mild and transient neurological disorders such as ataxia or tremor may occur in very rare cases. These effects are thought to occur as a result of the cat licking the application site immediately after treatment. In very rare cases following administration of Profender transient alopecia, pruritus and/or inflammation were observed at the application site.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 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.

4.9 Amounts to be administered and administration route

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 Profender / kg body weight.

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

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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

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, 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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole
Isopropylidene glycerol
Lactic acid

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Pack sizes	0.35 ml, 0.70 ml and 1.12 ml per pipette Blister packs containing 2, 4, 12, 20, or 40 unit dose pipettes; 0.70 ml pipette only: additional blister pack containing 80 pipettes
Container	White polypropylene pipettes with caps in aluminium blisters

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Profender should not be allowed to enter water courses as emodepside has shown harmful effects on aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/001-016

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27/07/2005.
Date of last renewal: 01/07/2010.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

[Multi-dose bottle]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 85.8 mg/ml / 21.4 mg/ml spot-on solution for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Profender contains 21.4 mg/ml emodepside and 85.8 mg/ml praziquantel.

Excipients:

5.4 mg/ml butylhydroxyanisole (E320; as antioxidant)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution.
Clear yellow to brown solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the 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)

4.3 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.

4.4 Special warnings for each target species

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.

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

4.5 Special precautions for use

Special precautions for use in animals

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 product in sick and debilitated animals, thus the 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 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 product.

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.

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.

4.6 Adverse reactions (frequency and seriousness)

Salivation and vomiting may occur in very rare cases. Mild and transient neurological disorders such as ataxia or tremor may occur in very rare cases. These effects are thought to occur as a result of the cat licking the application site immediately after treatment. In very rare cases following administration of Profender transient alopecia, pruritus and/or inflammation were observed at the application site.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 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.

4.9 Amounts to be administered and administration route

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 Profender / kg body weight.

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_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

For external use only.

Take the adapter, remove protective cover from the spike and insert spike into the central area of the stopper. Remove screw cap. Take a standard disposable 1 ml syringe with luer nozzle and connect it to the adapter. Then turn bottle up-side down, and withdraw the necessary volume. 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.
Application on the base of the skull will minimise the ability of the cat to lick the product off.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

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*, *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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole
Isopropylidene glycerol
Lactic acid

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Shelf life after first opening the immediate packaging: 3 months

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Pack size: 14 ml
Container: Amber coloured glass bottle with teflon-coated stopper and micro-spike adapter with luer-port

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Profender should not be allowed to enter water courses as emodepside has shown harmful effects on aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/017

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27/07/2005.
Date of last renewal: 01/07/2010.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

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. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet of Profender contains:

Active substances:

	Emodepside	**Praziquantel**
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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the 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)

4.3 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.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

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 (OIE), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

4.6 Adverse reactions (frequency and seriousness)

Transient mild digestive tract disorders (e.g. hypersalivation, vomiting) were observed in very rare cases.
Transient mild neurological disorders (e.g. tremors, incoordination) were observed in very rare cases. Non compliance with fasting requirements tended to be a feature of those cases. In addition, signs of neurological disorders may be more severe (e.g. convulsion) in mdr1 mutant (-/-) Collies, Shelties and Australian Shepherds.
Specific antidotes are not known.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy or lactation

Can be used during pregnancy and lactation.

4.8 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.

4.9 Amounts to be administered and administration route

Dosage and Treatment Schedule

Profender 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 Profender tablets for**		
	small dogs 1  **= 3 kg**	**medium dogs** 1  **= 10 kg**	**large dogs** 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. Profender 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

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 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.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium hydrogen phosphate anhydrous
Cellulose, microcrystalline
Silica, colloidal anhydrous
Croscarmellose sodium
Magnesium stearate
Povidone
Artificial beef flavour

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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

Profender 15 mg/3 mg 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 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 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Unused half tablets must not be stored for future use and should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/018 - 031

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 27/07/2005.
Date of last renewal: 01/07/2010.

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
Germany

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender spot-on solution for small cats
Outer carton, pack size of 2 (or 4) pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 30 mg/7.5 mg spot-on solution for small cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.35 ml pipette contains:
Active substances: 7.5 mg emodepside, 30 mg praziquantel

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZES

2 pipettes
4 pipettes

5. TARGET SPECIES

For small cats ≥ 0.5 kg – 2.5 kg

6. INDICATION(S)

Roundworms:
Toxocara cati, Toxascaris leonina, Ancylostoma tubaeforme

Tapeworms:
Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis

Lungworms:
Aelurostrongylus abstrusus

For the complete indication, including the larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/001 2 pipettes
EU/2/05/054/002 4 pipettes

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender spot-on solution for small cats
Outer carton, pack size of 12 (20 or 40) pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 30 mg/7.5 mg spot-on solution for small cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.35 ml pipette contains:
Active substances: 7.5 mg emodepside, 30 mg praziquantel

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZES

12 pipettes
20 pipettes
40 pipettes

5. TARGET SPECIES

For small cats ≥ 0.5 kg – 2.5 kg

6. INDICATION(S)

Roundworms:
Toxocara cati, Toxascaris leonina, Ancylostoma tubaeforme

Tapeworms:
Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis

Lungworms:
Aelurostrongylus abstrusus

For the complete indication, including the larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in kittens under 8 weeks of age or weighing less than 0.5 kg.
For user safety warnings – read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Profender should not be allowed to enter water courses as emodepside has shown harmful effects on aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/003 12 pipettes
EU/2/05/054/004 20 pipettes
EU/2/05/054/005 40 pipettes

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender spot-on solution for medium cats
Outer carton, pack size of 2 (or 4) pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 60 mg/15 mg spot-on solution for medium cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.70 ml pipette contains:
Active substances: 15 mg emodepside, 60 mg praziquantel

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZES

2 pipettes
4 pipettes

5. TARGET SPECIES

For medium cats > 2.5 kg – 5 kg

6. INDICATION(S)

Roundworms:
Toxocara cati, Toxascaris leonina, Ancylostoma tubaeforme

Tapeworms:
Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis

Lungworms:
Aelurostrongylus abstrusus

For the complete indication, including the larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/006 2 pipettes
EU/2/05/054/007 4 pipettes

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender spot-on solution for medium cats
Outer carton, pack size of 12 (20, 40 or 80) pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 60 mg/15 mg spot-on solution for medium cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.70 ml pipette contains:
Active substances: 15 mg emodepside, 60 mg praziquantel

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZES

12 pipettes
20 pipettes
40 pipettes
80 pipettes

5. TARGET SPECIES

For medium cats > 2.5 kg – 5 kg

6. INDICATION(S)

Roundworms:
Toxocara cati, Toxascaris leonina, Ancylostoma tubaeforme

Tapeworms:
Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis

Lungworms:
Aelurostrongylus abstrusus

For the complete indication, including the larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in kittens under 8 weeks of age or weighing less than 0.5 kg.
For user safety warnings – read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Profender should not be allowed to enter water courses as emodepside has shown harmful effects on aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE,IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/008 12 pipettes
EU/2/05/054/009 20 pipettes
EU/2/05/054/010 40 pipettes
EU/2/05/054/011 80 pipettes

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender spot-on solution for large cats
Outer carton, pack size of 2 (or 4) pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 96 mg/24 mg spot-on solution for large cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1.12 ml pipette contains:
Active substances: 24 mg emodepside, 96 mg praziquantel

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZES

2 pipettes
4 pipettes

5. TARGET SPECIES

For large cats > 5 kg – 8 kg

6. INDICATION(S)

Roundworms:
Toxocara cati, Toxascaris leonina, Ancylostoma tubaeforme

Tapeworms:
Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis

Lungworms:
Aelurostrongylus abstrusus

For the complete indication, including the larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/012 2 pipettes
EU/2/05/054/013 4 pipettes

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender spot-on solution for large cats
Outer carton, pack size of 12 (20 or 40) pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 96 mg/24 mg spot-on solution for large cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1.12 ml pipette contains:
Active substances: 24 mg emodepside, 96 mg praziquantel

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZES

12 pipettes
20 pipettes
40 pipettes

5. TARGET SPECIES

For large cats > 5 kg – 8 kg

6. INDICATION(S)

Roundworms:
Toxocara cati, Toxascaris leonina, Ancylostoma tubaeforme

Tapeworms:
Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis

Lungworms:
Aelurostrongylus abstrusus

For the complete indication, including the larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in kittens under 8 weeks of age or weighing less than 0.5 kg.
For user safety warnings – read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Profender should not be allowed to enter water courses as emodepside has shown harmful effects on aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/014 12 pipettes
EU/2/05/054/015 20 pipettes
EU/2/05/054/016 40 pipettes

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender spot-on solution for cats
Outer carton, Multi-dose bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 85.8 mg/ml / 21.4 mg/ml spot-on solution for cats

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances: 21.4 mg/ml emodepside, 85.8 mg/ml praziquantel

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

14 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

Roundworms:
Toxocara cati, Toxascaris leonina, Ancylostoma tubaeforme

Tapeworms:
Dipylidium caninum, Taenia taeniaeformis, Echinococcus multilocularis

Lungworms:
Aelurostrongylus abstrusus

For the complete indication, including the larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

For user safety warnings – read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate container: 3 months

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/017

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Profender spot-on solution for small cats
Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender for cats (≥ 0.5–2.5 kg)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

Spot-on

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Profender spot-on solution for medium cats
Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender for cats (> 2.5–5 kg)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

Spot-on

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Profender spot-on solution for large cats
Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender for cats (> 5–8 kg)

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

Spot-on

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Profender spot-on solution for cats
Bottle label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender spot-on solution for cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

21.4 mg/ml emodepside, 85.8 mg/ml praziquantel

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

14 ml

4. ROUTE(S) OF ADMINISTRATION

Spot-on use.
For external use only.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

Once opened, use by……{leave space for the date to be inserted}.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Profender spot-on solution for small cats
blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender spot-on solution for small cats (≥0.5-2.5 kg)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Lot: {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Profender spot-on solution for medium cats
blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender spot-on solution for medium cats (>2.5-5 kg)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Lot: {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Profender spot-on solution for large cats
blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender spot-on solution for large cats (> 5-8 kg)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

Lot: {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender 15 mg / 3 mg Tablets for Small Dogs
Outer carton, pack size of 2 (or 4) tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 15 mg / 3 mg modified-release Tablets for Small Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

3 mg emodepside, 15 mg praziquantel.

3. PHARMACEUTICAL FORM

Modified-release tablet

4. PACKAGE SIZE

2 tablets
4 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Dewormer against roundworms and tapeworms.
For the complete indication, including species and larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/018 2 tablets
EU/2/05/054/019 4 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender 15 mg / 3 mg Tablets for Small Dogs
Outer carton, pack size of 10 (24 or 50) tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 15 mg / 3 mg modified-release Tablets for Small Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

3 mg emodepside, 15 mg praziquantel.

3. PHARMACEUTICAL FORM

Modified-release tablet

4. PACKAGE SIZE

10 tablets
24 tablets
50 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Dewormer against roundworms and tapeworms.
For the complete indication, including species and larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/020 10 tablets
EU/2/05/054/021 24 tablets
EU/2/05/054/022 50 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender 50 mg / 10 mg Tablets for Medium Dogs
Outer carton, pack size of 2 (or 4) tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 50 mg / 10 mg modified-release Tablets for Medium Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

10 mg emodepside, 50 mg praziquantel.

3. PHARMACEUTICAL FORM

Modified-release tablet

4. PACKAGE SIZE

2 tablets
4 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Dewormer against roundworms and tapeworms.
For the complete indication, including species and larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/023 2 tablets
EU/2/05/054/024 4 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender 50 mg / 10 mg Tablets for Medium Dogs
Outer carton, pack size of 6 (24 or 102) tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 50 mg / 10 mg modified-release Tablets for Medium Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

10 mg emodepside, 50 mg praziquantel.

3. PHARMACEUTICAL FORM

Modified-release tablet

4. PACKAGE SIZE

6 tablets
24 tablets
102 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Dewormer against roundworms and tapeworms.
For the complete indication, including species and larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/025 6 tablets
EU/2/05/054/026 24 tablets
EU/2/05/054/027 102 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender 150 mg / 30 mg Tablets for Large Dogs
Outer carton, pack size of 2 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 150 mg / 30 mg modified-release Tablets for Large Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

30 mg emodepside, 150 mg praziquantel.

3. PHARMACEUTICAL FORM

Modified-release tablet

4. PACKAGE SIZE

2 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Dewormer against roundworms and tapeworms.
For the complete indication, including species and larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/028 2 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender 150 mg / 30 mg Tablets for Large Dogs
Outer carton, pack size of 4 (24 or 52) tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 150 mg / 30 mg modified-release Tablets for Large Dogs

2. STATEMENT OF ACTIVE SUBSTANCES

30 mg emodepside, 150 mg praziquantel.

3. PHARMACEUTICAL FORM

Modified-release tablet

4. PACKAGE SIZE

4 tablets
24 tablets
52 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

Dewormer against roundworms and tapeworms.
For the complete indication, including species and larval stages, read the package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A., Magny-Vernois, 70200 Lure, France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/029 4 tablets
EU/2/05/054/030 24 tablets
EU/2/05/054/031 52 tablets

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Profender 15 mg / 3 mg Tablets for Small Dogs
Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender Tablets for Small Dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Profender 50 mg / 10 mg Tablets for Medium Dogs
Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender Tablets for Medium Dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS
Profender 150 mg / 30 mg Tablets for Large Dogs
Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender Tablets for Large Dogs

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

[Single-dose pipettes]

PACKAGE LEAFLET
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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

Manufacturer responsible for batch release:
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
Germany

2. 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
Praziquantel / Emodepside

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Active substances:

Profender contains 21.4 mg/ml emodepside and 85.8 mg/ml praziquantel.

Each unit dose (pipette) of Profender 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:

5.4 mg/ml butylhydroxyanisole (E320; as antioxidant)

4. INDICATIONS

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. ADVERSE REACTIONS

Salivation and vomiting may occur in very rare cases. Mild and transient neurological disorders such as ataxia or tremor may occur in very rare cases. These effects are thought to occur as a result of the cat licking the application site immediately after treatment. In very rare cases following administration of Profender transient alopecia, pruritus and/or inflammation were observed at the application site.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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 Profender / kg body weight.

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			

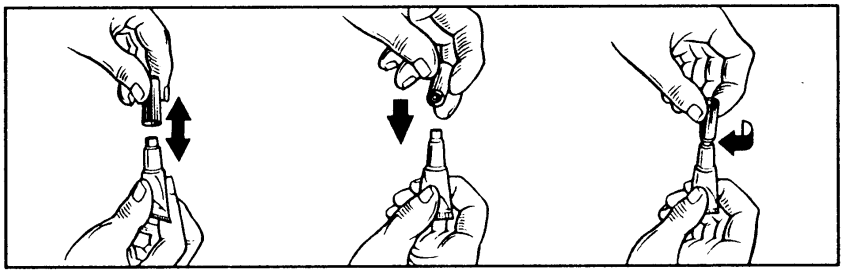
For the treatment of roundworms and tapeworms a single administration per treatment is effective.

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.

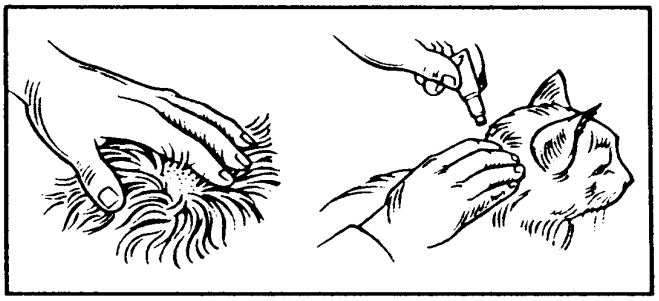
For the lungworm *Aelurostrongylus abstrusus*, two treatments administered two weeks apart are effective.

9. ADVICE ON CORRECT 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. Apply only to the skin surface and on intact skin.



10. WITHDRAWAL PERIOD(S)

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

12. SPECIAL WARNINGS

Special warnings for each target species:
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.

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

Special precautions for use in animals:
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 product in sick and debilitated animals, thus the 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 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 product.

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.

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.

Pregnancy and lactation:
Profender 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 (symptoms, emergency procedures, antidotes):

Salivation, vomiting and trembling 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.

Incompatibilities:
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Profender should not be allowed to enter water courses as emodepside has shown harmful effects on aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Not all pack sizes may be marketed.

[Multi-dose bottle]

PACKAGE LEAFLET
Profender 85.8 mg/ml / 21.4 mg/ml spot-on solution for cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

Manufacturer responsible for batch release:
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 85.8 mg/ml / 21.4 mg/ml spot-on solution for cats
Praziquantel/Emodepside

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Active substances:

Profender contains 21.4 mg/ml emodepside and 85.8 mg/ml praziquantel.

Excipients:

5.4 mg/ml butylhydroxyanisole (E320; as antioxidant)

4. INDICATIONS

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. ADVERSE REACTIONS

Salivation and vomiting may occur in very rare cases. Mild and transient neurological disorders such as ataxia or tremor may occur in very rare cases. These effects are thought to occur as a result of the cat licking the application site immediately after treatment. In very rare cases following administration of Profender transient alopecia, pruritus and/or inflammation were observed at the application site.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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 Profender / kg body weight.

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				

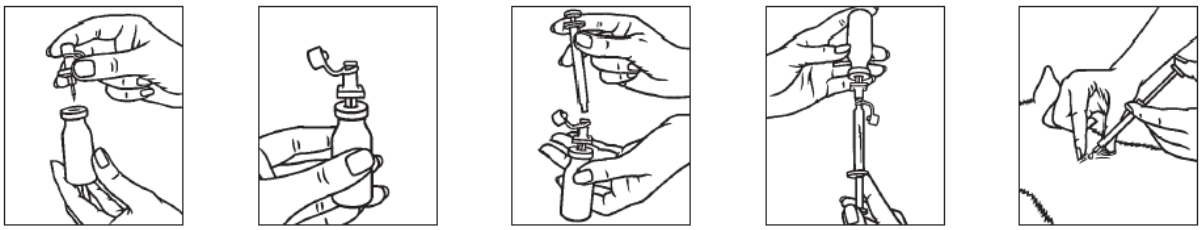
For the treatment of roundworms and tapeworms a single administration per treatment is effective.

For the treatment of queens to prevent lactogenic transmission of *Toxocara cati* (L_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.

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 product off. Apply only to the skin surface and on intact skin.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate container: 3 months

12. SPECIAL WARNING(S)

Special warnings for each target species:
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.

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

Special precautions for use in animals:
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 product in sick and debilitated animals, thus the 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 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 product.

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.

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.

Pregnancy and lactation:
Profender 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:
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.

Incompatibilities:
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Profender should not be allowed to enter water courses as emodepside has shown harmful effects on aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

Not all pack sizes may be marketed.

PACKAGE LEAFLET
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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Marketing authorisation holder:
Vetoquinol S.A.
Magny-Vernois
70200 Lure
France

Manufacturer responsible for batch release:
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324
24106 Kiel
Germany

2. 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
Praziquantel / Emodepside

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each tablet of Profender contains:

	Emodepside	**Praziquantel**
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

4. INDICATIONS

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. ADVERSE REACTIONS

Transient mild digestive tract disorders (e.g. hypersalivation, vomiting) were observed in very rare cases.
Transient mild neurological disorders (e.g. tremors, incoordination) were observed in very rare cases. Non compliance with fasting requirements tended to be a feature of those cases. In addition, signs of neurological disorders may be more severe (e.g. convulsion) in mdr1 mutant (-/-) Collies, Shelties and Australian Shepherds.
Specific antidotes are not known.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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

Profender 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 Profender tablets for		
	small dogs 1  **= 3 kg**	**medium dogs** 1  **= 10 kg**	**large dogs** 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

9. ADVICE ON CORRECT ADMINISTRATION

Profender 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.

10. WITHDRAWAL PERIOD(S)

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

12. SPECIAL WARNINGS

Special warnings for each target species:
Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class.

Special precautions for use in animals:
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 (OIE), 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:
Profender 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 (symptoms, emergency procedures, 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 frequency and intensity of such overdose symptoms and occasionally vomiting may occur.
Specific antidotes are not known.

Incompatibilities:
Not applicable.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Unused half tablets must not be stored for future use and should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

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.