ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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:

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

Each dosing unit (pipette) 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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisole (E320)	5.4 mg/ml
Isopropylidene glycerol	
Lactic acid	

Clear yellow to brown solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each 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)

3.3 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.

3.4 Special warnings

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

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

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with roundworms, tapeworms and lungworms should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.
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3.5 Special precautions for use

Special precautions for safe use in the target species:
Apply only to the skin surface and on intact skin. Do not administer orally or parenterally.

Avoid the treated cat or other cats in the household licking the site of application while it is wet.

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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 veterinary medicinal product accidentally gets into eyes, they should be thoroughly flushed with plenty of water.
If skin or eye symptoms persist, or in case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Care should be taken not to allow children to have prolonged intensive contact (for example, by sleeping) with treated cats during the first 24 hours after application of the veterinary medicinal product.

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the OIE, specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

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

Other precautions:
The solvent in this veterinary medicinal product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

3.6 Adverse events

Cats:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Neurological disorders[1,2,3] (ataxia[1,2,3], tremor[1,2,3]) Hypersalivation[3], vomiting[3], diarrhoea[3] Application site alopecia[2], application site pruritus, application site inflammation Behavioural disorders (hyperactivity, anxiety, vocalisation) Anorexia, lethargy

[1] Mild
[2] Transient
[3] These effects are thought to occur as a result of the cat licking the application site immediately after treatment

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Emodepside is a substrate for P-glycoprotein. Co-treatment with other veterinary medicinal products that are P-glycoprotein substrates/inhibitors (for example, ivermectin and other antiparasitic macrocyclic lactones, erythromycin, prednisolone and cyclosporine) could give rise to pharmacokinetic drug interactions. The potential clinical consequences of such interactions have not been investigated.

3.9 Administration routes and dosage

Spot-on use.
For external use only.

Dosage and treatment schedule

The recommended minimum doses are 3 mg emodepside / kg body weight and 12 mg praziquantel / kg body weight, equivalent to 0.14 ml of the veterinary medicinal product / kg body weight (bw).

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
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.

Underdosing could result in ineffective use and may favour resistance development

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

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

Salivation, vomiting and neurological signs (tremor) were observed occasionally when the veterinary medicinal product was administered at up to 10 times the recommended dose in adult cats and up to 5 times the recommended dose in kittens. These symptoms were thought to occur as a result of the cat licking the application site. The symptoms were completely reversible.
There is no known specific antidote.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AA51.

4.2 Pharmacodynamics

Emodepside is a semi-synthetic compound belonging to the new chemical group of depsipeptides. It is active against roundworms (ascarids and hookworms). In this veterinary medicinal 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.

4.3 Pharmacokinetics

After topical application of this veterinary medicinal 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

White polypropylene pipettes with caps in aluminium blisters

Blister packs in a cardboard box containing 2, 4, 12, 20 or 40 dose pipettes (0.35 ml each).
Blister packs in a cardboard box containing 2, 4, 12, 20, 40 or 80 dose pipettes (0.70 ml each).
Blister packs in a cardboard box containing 2, 4, 12, 20, or 40 dose pipettes (1.12 ml each).

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/001-016

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 27/07/2005.

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

[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:

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

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisole (E320)	5.4 mg/ml
Isopropylidene glycerol	
Lactic acid	

Clear yellow to brown solution.

3. CLINICAL PARTICULARS

3.1 Target species

Cats.

3.2 Indications for use for each 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)

3.3 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.

3.4 Special warnings

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

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

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with roundworms, tapeworms and lungworms should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Apply only to the skin surface and on intact skin. Do not administer orally or parenterally.

Avoid the treated cat or other cats in the household licking the site of application while it is wet.

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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 veterinary medicinal product accidentally gets into eyes, they should be thoroughly flushed with plenty of water.
If skin or eye symptoms persist, or in case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Care should be taken not to allow children to have prolonged intensive contact (for example, by sleeping) with treated cats during the first 24 hours after application of the product.

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.

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

Other precautions:
The solvent in this veterinary medicinal product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

3.6 Adverse events

Cats:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Neurological disorders[1,2,3] (ataxia[1,2,3], tremor[1,2,3]) Hypersalivation[3], vomiting[3], diarrhoea[3] Application site alopecia[2], application site pruritus, application site inflammation Behavioural disorders (hyperactivity, anxiety, vocalisation) Anorexia, lethargy

[1] Mild
[2] Transient
[3] These effects are thought to occur as a result of the cat licking the application site immediately after treatment

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Emodepside is a substrate for P-glycoprotein. Co-treatment with other veterinary medicinal products that are P-glycoprotein substrates/inhibitors (for example, ivermectin and other antiparasitic macrocyclic lactones, erythromycin, prednisolone and cyclosporine) could give rise to pharmacokinetic drug interactions. The potential clinical consequences of such interactions have not been investigated.

3.9 Administration routes and dosage

Spot-on use.
For external use only.

Dosage and treatment schedule
The recommended minimum doses are 3 mg emodepside / kg body weight and 12 mg praziquantel / kg body weight, equivalent to 0.14 ml of the veterinary medicinal product / kg body weight (bw).

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

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

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

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

Underdosing could result in ineffective use and may favour resistance development

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

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

Salivation, vomiting and neurological signs (tremor) were observed occasionally when the veterinary medicinal product was administered at up to 10 times the recommended dose in adult cats and up to 5 times the recommended dose in kittens. These symptoms were thought to occur as a result of the cat licking the application site. The symptoms were completely reversible.
There is no known specific antidote.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AA51.

4.2 Pharmacodynamics

Emodepside is a semi-synthetic compound belonging to the new chemical group of depsipeptides. It is active against roundworms (ascarids and hookworms). In this veterinary medicinal 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.

4.3 Pharmacokinetics

After topical application of this veterinary medicinal 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Amber coloured glass bottle with rubber stopper and micro-spike adapter with luer-port containing 14 ml.

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

Medicines should not be disposed of via wastewater or household waste.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/017

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 27/07/2005.

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

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 modified-release tablet 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

Excipients:

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

Brown, bone-shaped tablets with a score mark on each side.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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

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

Tapeworms (cestodes):
Dipylidium caninum

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

3.3 Contraindications

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

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

3.4 Special warnings

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

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with roundworms and tapeworms should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.

3.5 Special precautions for use

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

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

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the interests of good hygiene, wash your hands after administering the tablets to the dog.
In case of accidental ingestion, especially in the case of children, seek medical advice immediately and show the package leaflet or the label to the physician.

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the World Organisation for Animal Health (OIE), specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

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

3.6 Adverse events

Dogs:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorders[1] (e.g. hypersalivation, vomiting, diarrhoea) [1]

	Neurological disorders[1,2] (e.g. tremor, incoordination)[1,2], Convulsion[3] Behavioural disorders (e.g. hyperactivity) Anorexia, lethargy, recumbency, hyperthermia.

[1] Mild and transient
[2] Non-compliance with fasting requirements tended to be a feature of those cases
[3] Signs of neurological disorders may be more severe in mdr1 mutant (-/-) Collies, Shelties and Australian Shepherds. Specific antidotes are not known

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy or lactation

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Emodepside is a substrate for P-glycoprotein. Co-treatment with other drugs that are P-glycoprotein substrates/inhibitors (for example, ivermectin and other antiparasitic macrocyclic lactones, erythromycin, prednisolone and cyclosporine) could give rise to pharmacokinetic drug interactions. The potential clinical consequences of such interactions have not been investigated.

3.9 Administration routes and dosage

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

A single administration per treatment is effective.

Body Weight (kg)	**Number of modified-release tablets for**		
	small dogs **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. The veterinary medicinal product tablets are meat flavoured and usually dogs will accept them without any food.

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

Underdosing could result in ineffective use and may favour resistance development

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

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

Transient muscular tremors, incoordination and depression were occasionally observed when the veterinary product was administered at overdoses of up to 5 times the recommended dose. In mdr1 mutant (-/-) Collies the margin of safety appears lower compared to the normal dog population, with mild transient tremor and/or ataxia occasionally observed after twice the recommended dose, in dogs fasted as recommended.
The symptoms were completely self-resolving without any treatment. Feeding can increase the incidence and intensity of such overdose symptoms and occasionally vomiting may occur.
Specific antidotes are not known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AA51.

4.2 Pharmacodynamics

Emodepside is a semi-synthetic compound belonging to the new chemical group of depsipeptides. It is active against roundworms (ascarids, hookworms and whipworms). In this veterinary medicinal product, emodepside is responsible for the efficacy against *Toxocara canis, Toxascaris leonina, Ancylostoma caninum, Uncinaria stenocephala* and *Trichuris vulpis*.
It acts at the neuromuscular junction by stimulating presynaptic receptors belonging to the secretin receptor family which results in paralysis and death of the parasites.

Praziquantel is a pyrazinoisoquinoline derivative effective against tapeworms such as *Dipylidium caninum, Taenia* spp., *Echinococcus multilocularis* and *Echinococcus granulosus*.
Praziquantel is rapidly adsorbed via the surface of the parasites and acts primarily by changing the calcium (Ca^{++}) permeability of the parasite membranes. This results in severe damage to the parasite integument, contraction and paralysis, disruption of metabolism and finally leads to the death of the parasite.

4.3 Pharmacokinetics

After treatment with a dose of 1.5 mg emodepside and 7.5 mg praziquantel per kg bodyweight, geometric mean maximum plasma concentrations of 47 µg emodepside/l and 593 µg praziquantel/l were observed. Maximum concentrations were reached 2 hours after treatment for both active substances. Both active substances were then eliminated from the plasma with a half-life of 1.4 to 1.7 hours.

After oral application in the rat, emodepside is distributed to all organs. Highest concentration levels are found in the fat. Unchanged emodepside and hydroxylated derivatives are the major excretion products. The excretion of emodepside has not been investigated in dogs.
Studies in many different species show that praziquantel is rapidly metabolised in the liver. The main metabolites are monohydroxycyclohexyl derivatives of praziquantel. Renal excretion of metabolites predominates.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

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

5.3 Special precautions for storage

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

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

Profender 50 mg/10 mg tablets for medium dogs

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

Profender 150 mg/30 mg tablets for large dogs

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

Not all pack sizes may be marketed.

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

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/054/018 - 031

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 27/07/2005.

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

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender spot-on solution for small cats
Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 30 mg / 7.5 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

2 pipettes
4 pipettes
12 pipettes
20 pipettes
40 pipettes

4. TARGET SPECIES

For small cats

≥ 0.5 kg - 2.5 kg

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use
For external use only.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/05/054/001 2 pipettes
EU/2/05/054/002 4 pipettes
EU/2/05/054/003 12 pipettes
EU/2/05/054/004 20 pipettes
EU/2/05/054/005 40 pipettes

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender spot-on solution for medium cats
Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 60 mg / 15 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

2 pipettes
4 pipettes
12 pipettes
20 pipettes
40 pipettes
80 pipettes

4. TARGET SPECIES

For medium cats

> 2.5 kg - 5 kg

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Spot-on use
For external use only.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

14. MARKETING AUTHORISATION NUMBERS

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

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender spot-on solution for large cats
Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 96 mg / 24 mg spot-on solution

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

2 pipettes
4 pipettes
12 pipettes
20 pipettes
40 pipettes

4. TARGET SPECIES

For large cats

> 5 kg - 8 kg

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on use
For external use only.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/05/054/012 2 pipettes
EU/2/05/054/013 4 pipettes
EU/2/05/054/014 12 pipettes
EU/2/05/054/015 20 pipettes
EU/2/05/054/016 40 pipettes

15. 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

2. STATEMENT OF ACTIVE SUBSTANCES

21.4 mg/ml emodepside, 85.8 mg/ml praziquantel

3. PACKAGE SIZE

14 ml

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Spot-on solution
For external use only.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/05/054/017

15. BATCH NUMBER

Lot {number}

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 0.5 - 2.5 kg
Profender > 2.5 - 5 kg
Profender > 5 - 8 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.35 ml
0.70 ml
1.12 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Vetoquinol logo

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. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

21.4 mg/ml emodepside, 85.8 mg/ml praziquantel

14 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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

Vetoquinol logo

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 0.5 - 2.5 kg
Profender > 2.5 - 5 kg
Profender > 5 - 8 kg

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

7.5 mg emodepside / 30 mg praziquantel (EN)
15 mg emodepside / 60 mg praziquantel (EN)
24 mg emodepside / 96 mg praziquantel (EN)

3. BATCH NUMBER

Lot: {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Vetoquinol logo

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender 15 mg / 3 mg tablets for small dogs
Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 15 mg / 3 mg modified-release tablets

2. STATEMENT OF ACTIVE SUBSTANCES

3 mg emodepside, 15 mg praziquantel.

3. PACKAGE SIZE

2 modified-release tablets
4 modified-release tablets
10 modified-release tablets
24 modified-release tablets
50 modified-release tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

1 tablet = 3 kg

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/05/054/018 2 modified-release tablets
EU/2/05/054/019 4 modified-release tablets
EU/2/05/054/020 10 modified-release tablets
EU/2/05/054/021 24 modified-release tablets
EU/2/05/054/022 50 modified-release tablets

15. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender 50 mg / 10 mg tablets for medium dogs
Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 50 mg / 10 mg modified-release tablets

2. STATEMENT OF ACTIVE SUBSTANCES

10 mg emodepside, 50 mg praziquantel.

3. PACKAGE SIZE

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

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

1 tablet = 10 kg

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/05/054/023 2 modified-release tablets
EU/2/05/054/024 4 modified-release tablets
EU/2/05/054/025 6 modified-release tablets
EU/2/05/054/026 24 modified-release tablets
EU/2/05/054/027 102 modified-release tablets

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Profender 150 mg / 30 mg tablets for large dogs
Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender 150 mg / 30 mg modified-release tablets

2. STATEMENT OF ACTIVE SUBSTANCES

30 mg emodepside, 150 mg praziquantel.

3. PACKAGE SIZE

2 modified-release tablets
4 modified-release tablets
24 modified-release tablets
52 modified-release tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

1 tablet = 30 kg

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/05/054/028 2 modified-release tablets
EU/2/05/054/029 4 modified-release tablets
EU/2/05/054/030 24 modified-release tablets
EU/2/05/054/031 52 modified-release tablets

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Profender tablets for dogs
Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Profender tablets for small dogs
Profender tablets for medium dogs
Profender tablets for large dogs

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

3 mg emodepside / 15 mg praziquantel (EN)
10 mg emodepside / 50 mg praziquantel(EN)
30 mg emodepside / 150 mg praziquantel(EN)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Vetoquinol logo

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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. Composition

Active substances:

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

Each dosing unit (pipette) 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:

Butylhydroxyanisole (E320) ……...5.4 mg/ml

Clear yellow to brown solution.

3. Target species

Cats.

4. Indications for use

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

Roundworms (nematodes)
Toxocara cati (mature adult, immature adult, L4 and L3)
Toxocara cati (L3 larvae) - treatment of queens during late pregnancy to prevent lactogenic transmission to the offspring
Toxascaris leonina (mature adult, immature adult and L4)
Ancylostoma tubaeforme (mature adult, immature adult and L4)

Tapeworms (cestodes)
Dipylidium caninum (mature adult and immature adult)

Taenia taeniaeformis (adult)
Echinococcus multilocularis (adult)

Lungworms
Aelurostrongylus abstrusus (adult)

5. Contraindications

Do not use in kittens under 8 weeks of age or weighing less than 0.5 kg.
Do not use in cases of hypersensitivity to the active substances or to any of the excipients.

6. Special warnings

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

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

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with roundworms, tapeworms and lungworms should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.

Special precautions for safe use in the target species:
Apply only to the skin surface and on intact skin. Do not administer orally or parenterally.

Avoid the treated cat or other cats in the household licking the site of application while it is wet.

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke, eat or drink during application.
Avoid direct contact with application area while it is wet. Keep children away from treated animals during that time.
Wash hands after use.
In case of accidental spillage onto skin, wash off immediately with soap and water.
If the veterinary medicinal product accidentally gets into eyes, they should be thoroughly flushed with plenty of water.
If skin or eye symptoms persist, or in case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Care should be taken not to allow children to have prolonged intensive contact (for example, by sleeping) with treated cats during the first 24 hours after application of the veterinary medicinal product.

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the OIE, specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

Other precautions:
The solvent in this veterinary medicinal product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Emodepside is a substrate for P-glycoprotein. Co-treatment with other veterinary medicinal products that are P-glycoprotein substrates/inhibitors (for example, ivermectin and other antiparasitic macrocyclic lactones, erythromycin, prednisolone and cyclosporine) could give rise to pharmacokinetic drug interactions. The potential clinical consequences of such interactions have not been investigated.

Overdose:
Salivation, vomiting and trembling were observed occasionally when the veterinary medicinal product was administered at up to 10 times the recommended dose in adult cats and up to 5 times the recommended dose in kittens. These symptoms were thought to occur as a result of the cat licking the application site. The symptoms were completely reversible.
There is no known specific antidote.

Major incompatibilities:
None known.

7. Adverse events

Cats:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Neurological disorders[1,2,3] (ataxia[1,2,3] (incoordination) tremor[1,2,3]) Hypersalivation[3], vomiting[3], diarrhoea[3] Application site alopecia[2] (hair loss), application site pruritus (itching), application site inflammation Behavioural disorders (hyperactivity, anxiety, vocalisation) Anorexia, lethargy

[1] Mild
[2] Transient
[3] These effects are thought to occur as a result of the cat licking the application site immediately after treatment

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Spot-on use.

For external use only.

Dosage and treatment schedule
The recommended minimum doses are 3 mg emodepside / kg body weight and 12 mg praziquantel / kg body weight, equivalent to 0.14 ml of the veterinary medicinal product / kg body weight (bw).

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			

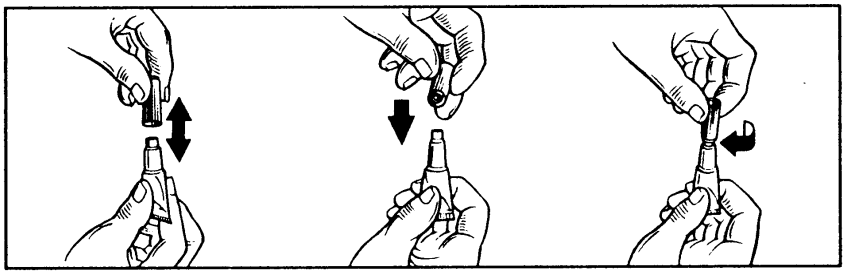
For the treatment of roundworms and tapeworms a single administration per treatment is effective.

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.

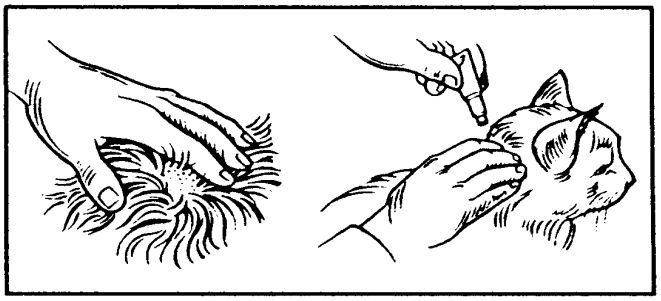
For the lungworm *Aelurostrongylus abstrusus*, two treatments administered two weeks apart are effective.

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



Underdosing could result in ineffective use and may favour resistance development

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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 after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/05/054/001-016

White polypropylene pipettes with caps in aluminium blisters

Blister packs in a cardboard box containing 2, 4, 12, 20 or 40 dose pipettes (0.35 ml each).
Blister packs in a cardboard box containing 2, 4, 12, 20, 40 or 80 dose pipettes (0.70 ml each).
Blister packs in a cardboard box containing 2, 4, 12, 20, or 40 dose pipettes (1.12 ml each).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
Vetoquinol S.A.
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PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Active substances:

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

Excipients:

Butylhydroxyanisole (E320; as antioxidant) ……...5.4 mg/ml

Clear yellow to brown solution.

3. Target species

Cats.

4. Indications for use

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

Roundworms (nematodes)
Toxocara cati (mature adult, immature adult, L4 and L3)
Toxocara cati (L3 larvae) - treatment of queens during late pregnancy to prevent lactogenic transmission to the offspring
Toxascaris leonina (mature adult, immature adult and L4)
Ancylostoma tubaeforme (mature adult, immature adult and L4)

Tapeworms (cestodes)
Dipylidium caninum (mature adult and immature adult)
Taenia taeniaeformis (adult)
Echinococcus multilocularis (adult)

Lungworms
Aelurostrongylus abstrusus (adult)

5. Contraindications

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

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

6. Special warnings

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

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

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with roundworms, tapeworms and lungworms should be considered, and these should be treated as necessary with an appropriate veterinaty medicinal product.

Special precautions for safe use in the target species:
Apply only to the skin surface and on intact skin. Do not administer orally or parenterally.

Avoid the treated cat or other cats in the household licking the site of application while it is wet.

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not smoke, eat or drink during application.
Avoid direct contact with application area while it is wet. Keep children away from treated animals during that time.
Wash hands after use.
In case of accidental spillage onto skin, wash off immediately with soap and water.
If the veterinary medicinal product accidentally gets into eyes, they should be thoroughly flushed with plenty of water.
If skin or eye symptoms persist, or in case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Care should be taken not to allow children to have prolonged intensive contact (for example, by sleeping) with treated cats during the first 24 hours after application of the veterinary medicinal product.

Echinococcosis represents a hazard for humans. As Echinococcosis is a notifiable disease to the OIE, specific guidelines on the treatment and follow-up, and on the safeguard of persons, need to be obtained from the relevant competent authority.

Other precautions:
The solvent in this veterinary medicinal product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Emodepside is a substrate for P-glycoprotein. Co-treatment with other veterinary medicinal products that are P-glycoprotein substrates/inhibitors (for example, ivermectin and other antiparasitic macrocyclic lactones, erythromycin, prednisolone and cyclosporine) could give rise to pharmacokinetic drug interactions. The potential clinical consequences of such interactions have not been investigated.

Overdose:
Salivation, vomiting and neurological signs (tremor) were observed occasionally when the veterinary medicinal product was administered at up to 10 times the recommended dose in adult cats and up to 5 times the recommended dose in kittens. These symptoms were thought to occur as a result of the cat licking the application site. The symptoms were completely reversible.
There is no known specific antidote.

Major incompatibilities:
None known.

7. Adverse events

Cats:

Very rare (< 1 animal / 10,000 animals treated, including isolated reports):	Neurological disorders[1,2,3] (ataxia[1,2,3] (incoordination) tremor[1,2,3]) Hypersalivation[3], vomiting[3], diarrhoea[3] Application site alopecia[2] (hair loss), application site pruritus (itching), application site inflammation Behavioural disorders (hyperactivity, anxiety, vocalisation) Anorexia, lethargy

[1] Mild
[2] Transient
[3] These effects are thought to occur as a result of the cat licking the application site immediately after treatment

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

Spot-on use.

For external use only.

Dosage and treatment schedule

The recommended minimum doses are 3 mg emodepside / kg body weight and 12 mg praziquantel / kg body weight, equivalent to 0.14 ml of the veterinary medicinal product / kg body weight (bw).

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

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

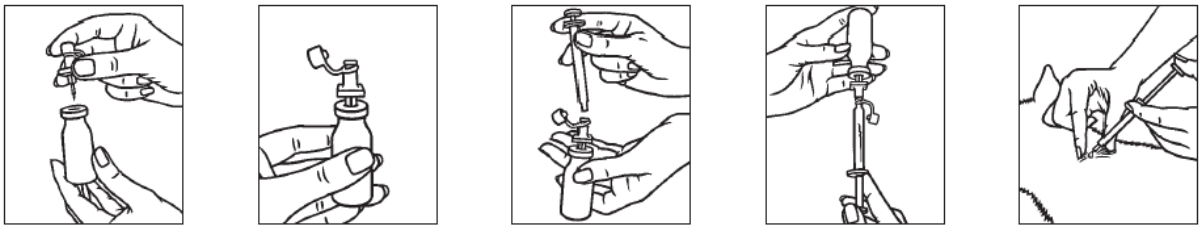
For the treatment of roundworms and tapeworms a single administration per treatment is effective.

For the treatment of queens to prevent lactogenic transmission of *Toxocara cati* (L_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 veterinary medicinal product off. Apply only to the skin surface and on intact skin.

Underdosing could result in ineffective use and may favour resistance development

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

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

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/05/054/017

Amber coloured glass bottle with rubber stopper and micro-spike adapter with luer-port containing 14 ml.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
Vetoquinol S.A.
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Manufacturer responsible for batch release:
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PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each modified-release tablet contains:

	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

Brown, bone-shaped tablets with a score mark on each side.

3. Target species

Dogs.

4. Indications for use

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

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

Tapeworms (cestodes):
Dipylidium caninum
Taenia spp.
Echinococcus multilocularis (mature adult and immature)
Echinococcus granulosus (mature adult and immature)

5. Contraindications

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

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

6. Special warnings

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

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infection based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infection with roundworms and tapeworms should be considered, and these should be treated as necessary with an appropriate veterinary medicinal product.

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

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

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

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the interests of good hygiene, wash your hands after administering the tablets to the dog. In case of accidental ingestion, especially in the case of children, seek medical advice 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:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Emodepside is a substrate for P-glycoprotein. Co-treatment with other drugs that are P-glycoprotein substrates/inhibitors (for example, ivermectin and other antiparasitic macrocyclic lactones, erythromycin, prednisolone and cyclosporine) could give rise to pharmacokinetic drug interactions. The potential clinical consequences of such interactions have not been investigated.

Overdose:
Transient muscular tremors, incoordination and depression were occasionally observed when the veterinary product was administered at overdoses of up to 5 times the recommended dose. In mdr1 mutant (-/-) Collies the margin of safety appears lower compared to the normal dog population, with mild transient tremor and/or ataxia occasionally observed after twice the recommended dose, in dogs fasted as recommended.
The symptoms were completely self-resolving without any treatment. Feeding can increase the frequency and intensity of such overdose symptoms and occasionally vomiting may occur.
Specific antidotes are not known.

Major incompatibilities:
Not applicable.

7. Adverse events

Dogs:

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

[1] Mild and transient
[2] Non-compliance with fasting requirements tended to be a feature of those cases
[3] Signs of neurological disorders may be more severe in mdr1 mutant (-/-) Collies, Shelties and Australian Shepherds. Specific antidotes are not known

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

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

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

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

A single administration per treatment is effective.

Body weight (kg)	**Number of modified-release tablets for**		
	small dogs **1 = 3 kg**	**medium dogs** **1 = 10 kg**	**large dogs** **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

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

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

Underdosing could result in ineffective use and may favour resistance development

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in the original package in order to protect from moisture.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton or blister after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/05/054/018-031

Pack sizes:

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

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

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

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

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

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

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
Vetoquinol S.A.
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70200 Lure
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Manufacturer responsible for batch release:
KVP Pharma + Veterinär Produkte GmbH
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