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Felpreva Spot-on Solution for Cats

Species: Cats

Therapeutic indication:Pharmaceuticals: Ectoparasiticides: For cats, **Pharmaceuticals: Endectocides:** For companion animals, **Pharmaceuticals: Endoparasiticides:** Anthelmintics for cats

Active ingredient: Emodepside, Praziquantel, Tigolaner

Product: Felpreva Spot-on Solution for Cats

Product index: Felpreva Spot-on Solution for Cats

Incorporating: Felpreva Spot-on Solution for Small Cats (1.0 - 2.5kg)

Felpreva Spot-on Solution for Medium Cats (>2.5 - 5.0kg)

Felpreva Spot-on Solution for Large Cats (>5.0 - 8.0kg)

Qualitative and quantitative composition

Active substances:

Each spot-on applicator delivers:

	Volume unit of dose (ml)	**Tigolaner**
Felpreva for small cats (1.0 - 2.5 kg)	0.37 ml	36.22 mg
Felpreva for medium cats (> 2.5 – 5.0 kg)	0.74 ml	72.45 mg
Felpreva for large cats (> 5.0 –8.0 kg)	1.18 ml	115.52 mg

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essentia the veterinary medicinal product
Butylhydroxyanisole (E320)	2.63 mg/ml
butylhydroxytoluene (E321)	1.10 mg/ml
Isopropylidene glycerol	
Lactic acid	

Pharmaceutical form

Clear yellow to red solution.

Change in colour may occur during storage. This phenomenon does not affect product quality.

Clinical particulars

Target species

Cats.

Indications for use for each target species

For cats with, or at risk from, mixed parasitic infestations/infections. The veterinary medicinal product is exclusively indicated when ectoparasites, cestodes and nematodes are targeted at the same time.

Ectoparasites

•For the treatment of flea (*Ctenocephalides felis*) and tick (*Ixodes ricinus, Ixodes holocyclus*) infestations in cats providing immediate and persistent killing activity for 13 weeks. · The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

•For the treatment of mild to moderate cases of notoedric mange (*Notoedres cati*).

•For the treatment of ear mite infestations (*Otodectes cynotis*)

Gastrointestinal roundworms (nematodes) For the treatment of infections with:

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

•*Toxascaris leonina* (mature adult, immature adult and L4)

•*Ancylostoma tubaeforme* (mature adult, immature adult and L4)

Lungworms (nematodes)

For the treatment of infections with:

•*Aelurostrongylus abstrusus* (adult)

•*Troglostrongylus brevior* (adult)

Tapeworms (cestodes)

For the treatment of tapeworm infections:

•*Dipylidium caninum* (mature adult and immature adult)

•*Taenia taeniaeformis* (adult)

Contraindications

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

Special warnings

Ectoparasites need to start feeding on the host to become exposed to tigolaner; therefore, the risk of the transmission of vector borne diseases cannot be excluded.

Parasite resistance to any particular class of antiparasitics included in the fixed combination may develop following frequent, repeated use of antiparasitics of those classes under specific circumstances. The use of this veterinary medicinal product should be based on the assessment of each individual case and on local epidemiological information about the current susceptibility of the target species in order to limit the possibility of a future selection for resistance.

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.

Special precautions for use

Special precautions for safe use in the target species:

In the absence of available data, treatment of kittens under 10 weeks of age or weighing less than 1 kg is not recommended.

This veterinary medicinal product is for topical use and should not be administered in any other way e.g. orally.

Apply only onto intact skin. Apply as described in section "Administration routes and dosage" to prevent the animal from licking and ingesting the veterinary medicinal product. Avoid the treated cat or other cats in the household licking the site of application while it is wet. For signs observed after oral ingestion (e.g. licking) please refer to section "Adverse events".

The product may be an eye irritant. If accidental ocular contact occurs, flush the eyes immediately with clean water. If eye irritation occurs, seek veterinary advice.

There is no 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.

Acute signs of pneumonia may occur after treatment as a result of the inflammatory host response against the death of *T. brevior* lungworms especially in young cats. The veterinary medicinal product should not be administered at intervals shorter than 8 weeks. Due to the product's activity against fleas and ticks for a period of 3 months from a clinical point of view, the use of the product is not indicated at intervals shorter than three months.

No target animal safety data beyond 4 consecutive treatments are available and accumulation of tigolaner is likely. Repeated treatments should be restricted to limited individual situations according to a benefit-risk evaluation by the responsible veterinarian. Please refer to "Symptoms of overdose" and "Pharmacokinetic" sections.

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

The veterinary medicinal product may cause neurological symptoms and can transiently elevate blood glucose levels following accidental ingestion.

Do not smoke, eat or drink during application. Wash hands after use.

Used applicators should be disposed of immediately and should not be left within the sight or reach of children.

In case of accidental contact of the applicator content to skin, wash off immediately with soap and water.

The veterinary medicinal product may be an eye irritant. 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, especially by children, seek medical advice immediately and show the package leaflet or the label to the physician.

Since foetotoxic effects are described in laboratory animals after exposure to tigolaner and emodepside, pregnant women and women intending to conceive should wear gloves to avoid direct contact with the product.

Pregnant women should avoid contact with the site of application during the first 24 hours after application of the product and until the treated area is no longer noticeable. Keep children away from treated animals during the first 24 hours after application of the product. Care should be taken not to allow children to have prolonged intensive contact with treated cats until the treated area is no longer noticeable. It is recommended to treat animals in the evening. On the day of treatment, treated animals should not be permitted to sleep in the same bed as their owner, especially children and pregnant women.

Special precautions for the protection of the environment:

Not applicable

Other precautions:

The veterinary medicinal product may stain or damage certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

Adverse events

Common (1 to 10 animals / 100 animals treated):	Hair change (e.g. spiking)1
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Application site reaction (scratc inflammation)2
	Digestive tract disorders (hypers
	Neurological disorders (ataxia, t
	Inappetence4

1 Cosmetic effect, temporary, at the application site

2 Mild and transient

3 After licking the application site immediately following treatment.

4 After licking, in individual cases

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system.

Use during pregnancy, lactation or lay

Pregnancy and lactation:

Foetotoxic effects are described in laboratory animals after exposure to tigolaner and emodepside. The safety of the veterinary medicinal product has not been established in pregnant or lactating cats and, therefore, use in such animals is not recommended.

Interaction with other medicinal products and other forms of interaction

Emodepside is a substrate for P-glycoprotein. Co-treatment with other substances 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.

Administration routes and dosage

Spot-on use. For external use only.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Posology

The recommended minimum doses are 14.4 mg tigolaner / kg body weight, 3 mg emodepside / kg body weight, 12 mg praziquantel / kg body weight equivalent to 0.148 ml product / kg body weight.

Body Weight of Cat (kg)	**Applicator size to be used:**	**Volume of unit (ml)**	**Tigolaner (mg/kg bw)**	**Emodeps bw)**
	Felpreva spot-on solution			
1.0 - 2.5	for small cats	0.37	14.5 - 36.2	3.0 - 7.5
2.6 - 5.0	for medium cats	0.74	14.5 - 27.9	3.0 - 5.8
5.1 - 8.0	for large cats	1.18	14.4 - 22.7	3.0 - 4.7
> 8.0	Use an appropriate combination of applicators			

Treatment schedule

Treatment is only indicated when ectoparasites, cestodes and nematodes are targeted at the same time. In the absence of mixed infections or risk of mixed infections, appropriate narrow spectrum antiparasitic products should be used.

Fleas and ticks

The veterinary medicinal product remains active against fleas and ticks for a period of 13 weeks.

If re-treatment is necessary within 13 weeks after administration, an appropriate narrow-spectrum product should be used.

Mites

For the treatment of ear mites (*Otodectes cynotis)* and notoedric mange (*Notoedres cati)* a single dose of the veterinary medicinal product should be administered.

The treatment success and the need for re-treatment with an appropriate narrow- spectrum antiparasitic product should be determined by the treating veterinarian after 4 weeks.

Due to individual cases of single surviving ear mites and, therefore, the risk of a new cycle of otocariosis, the treatment success should be confirmed by the veterinarian 1 month after treatment.

Gastrointestinal nematodes and tapeworms

For the treatment of roundworms and tapeworms a single dose of the veterinary medicinal product should be administered. The need for and frequency of re- treatment should be in accordance with

the advice of the prescribing veterinarian and take into account the local epidemiological situation as well as the cat's lifestyle.

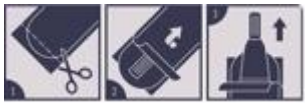
If a re-treatment is necessary within 3 months after administration, an appropriate narrow-spectrum product should be used.

Lungworms

For treatment against the lungworm *Aelurostrongylus abstrusus* and *Troglostrongylus brevior*, one treatment with the veterinary medicinal product followed by a second treatment two weeks apart with a spot-on solution for cats containing 21.4 mg/ml emodepside and 85.8 mg/ml praziquantel is recommended as there is no veterinary medicinal product containing only emodepside as active substance.

Method of administration

Use scissors (1) to open the childproof blister. Pull foils apart (2) and remove spot-on applicator from package (3).



Hold applicator in upright position (4), twist and pull off cap (5) and use the opposite end of the cap to break the seal (6).

Part the fur on the cat's neck at the base of the skull until the skin is visible (7). Place the tip of the applicator on the skin and squeeze firmly several times to empty the contents directly onto the skin (7). Application on the base of the skull will minimise the ability of the cat to lick the product off.

Symptoms of overdose (and where applicable, emergency proceduresand antidotes)

After administration of 4 consecutive treatments of up to 5 times the maximum recommended dose in kittens starting at 10 weeks of age and adult cats, a decrease in thyroid weight was noted in some male animals. In adult cats, a transient elevation in liver enzymes (AST, ALT), accompanied by multifocal liver congestion in one individual, was noted in the high dose group (5x) and an elevation in cholesterol in all overdose groups (3x, 5x). No systemic clinical signs were observed. In the high (5x)

dose group, cases of local reactions at the application site occurred (alopecia, erythema, hyperplasia of the epidermis

and/or inflammatory infiltrates). There is no antidote known.

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

Withdrawal period(s)

Not applicable.

Pharmacological particulars

Pharmacodynamics

Tigolaner belongs to the chemical class of bispyrazoles. Tigolaner acts as a potent inhibitor of the neurotransmitter gamma-aminobutyric acid (GABA) receptor.

Tigolaner exhibits higher functional potency to block insect/acarine receptors compared to mammalian receptors *in vitro*. It is an acaricide and insecticide and is efficacious against ticks (*Ixodes ricinus, I. holocyclus*), fleas (*Ctenocephalides felis*), and mites (*Notoedres cati, Otodectes cynotis)* on cats.

Fleas already on the animal prior to administration are killed within 12 hours. For newly infecting fleas the onset of efficacy is within 8 hours for 2 months after product administration and within 24 hours afterwards. Fleas and ticks must attach to the host and start feeding in order to be exposed to tigolaner. *Ixodes ricinus* ticks on the animal prior to administration are killed within 24 hours. *Ixodes ricinus* ticks newly infested are killed within 48 hours for 13 weeks.

Emodepside is a semi-synthetic compound belonging to the chemical group of depsipeptides. It is active against all stages of roundworms (ascarids and hookworms). In this product, emodepside is responsible for the efficacy against *Toxocara cati*, *Toxascaris leonina*, *Ancylostoma tubaeforme, Aelurostrongylus abstrusus* and *Troglostrongylus brevior*.

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 the tapeworms *Dipylidium caninum*, 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.

Pharmacokinetics

After single topical administration of the veterinary medicinal product to cats, maximum tigolaner plasma concentrations of 1.35 mg/L were reached 12 days after dosing. Tigolaner plasma concentrations declined slowly with a mean half-life of 24 days. Emodepside reached maximum plasma concentrations of 0.044 mg/L 1.5 days after dosing. Emodepside plasma concentrations declined with a mean half-life of 14.5 days. Praziquantel reached maximum plasma concentrations of 0.048 mg/L already 5 hours after dosing. Praziquantel plasma concentrations declined with a mean half-life of 10 days. Individual variation in plasma concentrations and half-life was observed for all three substances. For tigolaner, a significant increase in half- life following repeated dosing was shown resulting in accumulation of tigolaner after 4 consecutive treatments in cats.

Tigolaner and emodepside are poorly metabolized and mainly excreted in the feces. Renal clearance is the minor route of elimination. Praziquantel undergoes substantial hepatic metabolism and only traces are excreted equally via urine and feces.

Pharmaceutical particulars

Major incompatibilities

None known.

Shelf life

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

Special precautions for storage

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

Keep the applicator in the aluminium blister in order to protect from moisture.

Nature and composition of immediate packaging

Felpreva for small cats (1.0 -2.5kg) = 0.37 ml per pipette

Felpreva for medium cats (>2.5 - 5.0kg) = 0.74ml per pipette

Felpreva for large cats (>5.0 - 8.0kg) = 1.18ml per pipette

White polypropylene applicator with polypropylene cap in aluminium blister. Blister packs in a cardboard box containing 1, 2, 10 or 20 applicator(s).

Not all pack sizes may be marketed.

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.

The veterinary medicinal product should not enter water courses as tigolaner, emodepside, and praziquantel 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.

Marketing Authorisation Holder (if different from distributor)

Vetoquinol SA

Marketing Authorisation Number

Felpreva Spot-on Solution for Small Cats (1.0 -2.5 kg)

UK (GB): Vm 06462/5016

UK (NI): EU/2/21/277/001-004

Felpreva Spot-on Solution for Medium Cats (>2.5 - 5.0 kg)

UK (GB): Vm 06462/5017

UK (NI): EU/2/21/277/005-008

Felpreva Spot-on Solution for Large Cats (>5.0 - 8.0 kg)

UK (GB): Vm 06462/5018

UK (NI): EU/2/21/277/009-012

Significant changes

Date of the first authorisation or date of renewal

18 November 2021

Date of revision of the text

April 2025

Any other information

Legal category

Legal category:POM-V

GTIN

GTIN description: Felpreva for small cats

GTIN:03605870106127

GTIN description: Felpreva for medium cats

NOAH Compendium

GTIN:03605870106233

GTIN description: Felpreva for large cats

GTIN:03605870106455