Zoetis UK Limited

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Stronghold spot-on solution for cats & dogs (NI)

Species: Cats, Dogs

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

Active ingredient: Selamectin

Product: Stronghold® spot-on solution

Product index: Stronghold

Incorporating: Stronghold 15 mg spot-on solution for cats and dogs ≤ 2.5 kg

Stronghold 30 mg spot-on solution for dogs 2.6–5.0 kg

Stronghold 45 mg spot-on solution for cats 2.6–7.5 kg

Stronghold 60 mg spot-on solution for cats 7.6–10.0 kg

Stronghold 60 mg spot-on solution for dogs 5.1–10.0 kg

Stronghold 120 mg spot-on solution for dogs 10.1–20.0 kg

Stronghold 240 mg spot-on solution for dogs 20.1–40.0 kg

Stronghold 360 mg spot-on solution for dogs 40.1–60.0 kg

Qualitative and quantitative composition

Each single-dose (pipette) delivers:

Active substance:

	unit dose (ml)
Stronghold 15 mg for cats and dogs	0.25

Stronghold 30 mg for dogs	0.25	30
Stronghold 45 mg for cats	0.75	45
Stronghold 60 mg for cats	1	60
Stronghold 60 mg for dogs	0.5	60
Stronghold 120 mg for dogs	1	12
Stronghold 240 mg for dogs	2	24
Stronghold 360 mg for dogs	3	36

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is es veterinary medicinal product**
Butylated hydroxytoluene	0.8 mg/ml
Dipropylene glycol methyl ether	
Isopropyl alcohol	
Colourless to yellow solution.	

Pharmaceutical form

Please refer to the 'Qualitative and quantitative composition' section.

Clinical particulars

Target species

Dogs and cats.

Indications for use for each target species

Cats and dogs:

· **Treatment and prevention of flea infestations** caused by *Ctenocephalides* spp. for one month following a single administration. This is as a result of the adulticidal, larvicidal and ovicidal properties of the product. The product is ovicidal for 3 weeks after administration. Through a reduction in the flea population, monthly treatment of pregnant and lactating animals will also aid in the prevention of flea infestations in the litter up to seven weeks of age. The product can be used as part of a treatment strategy for flea allergy dermatitis and through its ovicidal and larvicidal action may aid in the control of existing environmental flea infestations in areas to which the animal has access.

· **Prevention of heartworm disease** caused by *Dirofilaria immitis* with monthly administration. The veterinary medicinal product may be safely administered to animals infected with adult heartworms, however, it is recommended, in accordance with good veterinary practice, that all animals 6 months

of age or more living in countries where a vector exists should be tested for existing adult heartworm infections before the administration of the veterinary medicinal product. It is also recommended that dogs should be tested periodically for adult heartworm infections, as an integral part of a heartworm prevention strategy, even when the veterinary medicinal product has been administered monthly. This product is not effective against adult *D. immitis*.

· **Treatment of ear mites** (*Otodectes cynotis*).

Cats:

· Treatment of biting lice infestations *(Felicola subrostratus*)

· Treatment of adult roundworms (*Toxocara cati*)

· Treatment of adult intestinal hookworms (*Ancylostoma tubaeforme)*.

Dogs:

· Treatment of biting lice infestations (*Trichodectes canis*)

· Treatment of sarcoptic mange (caused by *Sarcoptes scabiei*)

· Treatment of adult intestinal roundworms (*Toxocara canis*).

Contraindications

Do not use in animals under 6 weeks of age.

Do not use in cats that are suffering from concomitant disease, or are debilitated and underweight (for size and age).

Special warnings

Animals may be bathed 2 hours after treatment without loss of efficacy.

Do not apply when the animal's hair coat is wet. However, shampooing or soaking the animal 2 or more hours after treatment will not reduce the efficacy of the product.

For ear mite treatment, do not apply directly to the ear canal.

It is important to apply the dose as indicated to minimise the quantity that the animal can lick off. If significant licking does occur, a brief period of hypersalivation may rarely be observed in cats.

Special precautions for use

Special precautions for safe use in the target species:

This veterinary medicinal product is to be applied to the skin surface only. Do not administer orally or parenterally.

Keep treated animals away from fires and other sources of ignition for at least 30 minutes or until the hair coat is dry.

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

This product is highly flammable; keep away from heat, sparks, open flames or other sources of ignition.

Do not smoke, eat or drink while handling the product.

Wash hands after use and wash off any product in contact with the skin immediately with soap and water. In case of accidental eye exposure, flush the eyes immediately with water, seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid direct contact with treated animals until the application site is dry. On the day of treatment, children must not handle treated animals and the animals should not be permitted to sleep with their owners, especially children. Used applicators should be disposed of immediately and not left within the sight or reach of children.

People with sensitive skin or known allergy to veterinary medicinal products of this type should handle the veterinary medicinal product with caution.

Special precautions for the protection of the environment:

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

Other precautions:

Do not allow treated animals to bathe in water courses until at least two hours after treatment administration.

Adverse events

Cats:

Rare application site alopecia1,2, appl

(1 to 10 animals / 10 000 animals treated):

Very rare application site irritation1,4, neur

(<1 animal / 10 000 animals treated, including isolated reports):

Dogs:

Rare application sit

(1 to 10 animals / 10 000 animals treated):

Very rare neurological s

(<1 animal / 10 000 animals treated, including isolated reports):

1Normally self-resolving, but symptomatic therapy may be applicable in some circumstances.

2Mild and transient.

3Local temporary clumping of the hair at the application site and/or an occasional appearance of a small quantity of a white powder which typically disappear within 24 hours of treatment administration and does not affect either the safety or efficacy of the veterinary medicinal product.

4Transient and focal.

5Reversible as with other macrocyclic lactones.

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 also section 'Contact details' of the package leaflet.

Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used in pregnant and lactating cats and dogs.

Fertility:

Can be used in breeding cats and dogs.

Interaction with other medicinal products and other forms of interaction

In extensive field testing no interactions between this veterinary medicinal product and routinely used veterinary medicinal products or medical or surgical procedures were observed.

Administration routes and dosage

The veterinary medicinal product should be administered as a single application of a single dose delivering a minimum of 6 mg/kg selamectin. When concurrent infestations or infections in the same animal are to be treated with the veterinary medicinal product, only one application of the recommended 6 mg/kg dose should be administered at any one time. The appropriate length of the treatment period for individual parasites is specified below.

Administer in accordance with the following table:

Cats (kg)	**Pipette cap colour**	**mg of selamectin dispensed**	**Potency (mg/ml)**	**Administered**
≤ 2.5	Rose	15	60	0.25
2.6–7.5	Blue	45	60	0.75
7.6–10.0	Taupe	60	60	1.0
> 10		Appropriate combination	60	Appropriate co

		of pipettes		
Dogs (kg)	**Pipette cap colour**	**mg of selamectin dispensed**	**Potency (mg/ml)**	**Administered volume**
≤ 2.5	Rose	15	60	0.25
2.6–5.0	Violet	30	120	0.25
5.1–10.0	Brown	60	120	0.5
10.1–20.0	Red	120	120	1.0
20.1–40.0	Green	240	120	2.0
40.1–60.0	Plum	360	120	3.0
> 60		Appropriate combination of pipettes	60/120	Appropriate combinat

Flea treatment and prevention (cats and dogs)

Following administration of the veterinary medicinal product, the adult fleas on the animal are killed, no viable eggs are produced, and larvae (found only in the environment) are also killed. This stops flea reproduction, breaks the flea lifecycle and may aid in the control of existing environmental flea infestations in areas to which the animal has access.

For the prevention of flea infestations, the veterinary medicinal product should be administered at monthly intervals throughout the flea season, starting one month before fleas become active. Through a reduction in the flea population, monthly treatment of pregnant and lactating animals will aid prevention of flea infestations in the litter up to seven weeks of age.

For use as part of a treatment strategy for flea allergy dermatitis the veterinary medicinal product should be administered at monthly intervals.

Prevention of heartworm disease (cats and dogs)

The veterinary medicinal product may be administered year-round or at least within one month of the animal's first exposure to mosquitoes and monthly thereafter until the end of the mosquito season. The final dose must be given within one month after the last exposure to mosquitoes. If a dose is missed and a monthly interval between dosing is exceeded then immediate administration of the veterinary medicinal product and resumption of monthly dosing will minimise the opportunity for the development of adult heartworms. When replacing another heartworm preventive veterinary medicinal product in a heartworm disease prevention programme, the first dose of the veterinary medicinal product must be given within a month of the last dose of the former medication.

Treatment of roundworm infections (cats and dogs)

A single dose of the veterinary medicinal product should be administered.

Treatment of biting lice (cats and dogs)

A single dose of the veterinary medicinal product should be administered.

Treatment of ear mites (cats)

A single dose of the veterinary medicinal product should be administered.

Treatment of ear mites (dogs)

A single dose of the veterinary medicinal product should be administered. Loose debris should be gently removed from the external ear canal at the time of treatment. A further veterinary examination 30 days after treatment is recommended as some animals may require a second treatment.

Treatment of hookworm infections (cats)

A single dose of the veterinary medicinal product should be administered.

Treatment of sarcoptic mange (dogs)

For complete elimination of the mites, a single dose of the veterinary medicinal product should be administered for two consecutive months.

Method and route of administration:

Spot-on use.

Apply to the skin at the base of the neck in front of the shoulder blades.

How to apply:

Remove the pipette from its protective package

Holding the pipette upright, firmly depress the cap to puncture the applicator seal, then remove the ca

Part the hair at the base of your animal's neck in front of the shoulder blades to expose a small area of skin.

Apply the tip of the pipette directly to the skin without massaging. Squeeze the pipette firmly to empty the cor
spot. Avoid contact between the veterinary medicinal product and your fingers.

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

The veterinary medicinal product was administered at 10 times the recommended dose, and no undesirable effects were observed. The veterinary medicinal product was administered at 3 times the recommended dose to cats and dogs infected with adult heartworms and no undesirable effects were observed. The veterinary medicinal product was also administered at 3 times the recommended dose to breeding male and female cats and dogs, including pregnant and lactating females nursing their litters and at 5 times the recommended dose to ivermectin-sensitive Collies, and no undesirable effects were observed.

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 periods

Not applicable.

Pharmacological particulars

ATCvet code: QP54AA05.

Pharmacodynamics

Selamectin is a semi-synthetic compound of the avermectin class. Selamectin paralyses and/or kills a wide range of invertebrate parasites through interference with their chloride channel conductance causing disruption of normal neurotransmission. This inhibits the electrical activity of nerve cells in nematodes and muscle cells in arthropods leading to their paralysis and/or death.

Selamectin has adulticidal, ovicidal and larvicidal activity against fleas. Therefore, it effectively breaks the flea life cycle by killing adults (on the animal), preventing the hatching of eggs (on the

animal and in its environment) and by killing larvae (environment only). Debris from selamectin-treated pets kills flea eggs and larvae not previously exposed to selamectin and thus may aid in the control of existing environmental flea infestations in areas to which the animal has access.

Activity has also been demonstrated against heartworm larvae.

Pharmacokinetics

Following spot on administration selamectin is absorbed from the skin reaching maximum plasma concentrations approximately 1 and 3 days after administration in cats and dogs respectively. Following absorption from the skin selamectin distributes systemically and is slowly eliminated from plasma as manifested in detectable plasma concentrations in dogs and cats 30 days after administration of a single topical dose at 6 mg/kg. The prolonged persistence and slow elimination of selamectin from plasma is reflected in the terminal elimination half-life values of 8 and 11 days in cats and dogs respectively. The systemic persistence of selamectin in plasma and the lack of extensive metabolism provide effective concentrations of selamectin for the duration of the inter-dosing interval (30 days).

Pharmaceutical particulars

Major incompatibilities

Not applicable.

Shelf life

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

Special precautions for storage

Do not store above 30 °C.

Store in the original package in a dry place.

Nature and composition of immediate packaging

The veterinary medicinal product is available in packs of three pipettes (all pipette sizes), six pipettes (all pipette sizes except 15 mg selamectin), or fifteen pipettes (15 mg selamectin pipette size only). The veterinary medicinal product is in translucent polypropylene single-dose pipettes in an aluminium and aluminium/PVC blister overwrap.

Stronghold 15 mg spot-on solution for cats and dogs ≤ 2.5 kg: 0.25 ml per pipette

Stronghold 30 mg spot-on solution for dogs 2.6–5.0 kg: 0.25 ml per pipette

Stronghold 45 mg spot-on solution for cats 2.6–7.5 kg: 0.75 ml per pipette

Stronghold 60 mg spot-on solution for cats 7.6–10.0 kg: 1 ml per pipette

Stronghold 60 mg spot-on solution for dogs 5.1–10.0 kg: 0.5 ml per pipette

Stronghold 120 mg spot-on solution for dogs 10.1–20.0 kg: 1 ml per pipette

Stronghold 240 mg spot-on solution for dogs 20.1–40.0 kg: 2 ml per pipette

Stronghold 360 mg spot-on solution for dogs 40.1–60.0 kg: 3 ml per pipette

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 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.

Marketing Authorisation Holder (if different from distributor)

Zoetis Belgium

Marketing Authorisation Number

EU/2/99/014/001-016

Significant changes

Date of the first authorisation or date of renewal

Date of first authorisation: 25/11/1999.

Date of revision of the text

Any other information

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).

Legal category

Legal category:POM-V

GTIN

GTIN description:15 mg x 3 tubes:

GTIN:05013457078497

GTIN description:15 mg x 15 tubes:

GTIN:05414736013435

NOAH Compendium

GTIN description:30 mg x 3 tubes:

GTIN:05013457078510

GTIN description:30 mg x 6 tubes:

GTIN:05414736018461

GTIN description:45 mg x 3 tubes:

GTIN:05013457078503

GTIN description:45 mg x 6 tubes:

GTIN:05013457079449

GTIN description:60 mg (dog) x 3 tubes:

GTIN:05013457078527

GTIN description:60 mg (cat) x 3 tubes:

GTIN:05414736029146

GTIN description:60 mg x 6 tubes:

GTIN:05414736018478

GTIN description:120 mg x 3 tubes:

GTIN:05013457078534

GTIN description:120 mg x 6 tubes:

GTIN:05414736018454

GTIN description:240 mg x 3 tubes

GTIN:05013457078541

GTIN description:240 mg x 6 tubes:

GTIN:05414736018447

GTIN description:360 mg x 3 tubes:

GTIN:05414736029153