

## Stronghold Spot-On Solution for Cats & Dogs

**Species:**Cats, Dogs

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

**Active ingredient:**Selamectin

**Product:**Stronghold® Spot-On Solution

**Product index:**Stronghold

### Presentation

A colourless to yellow ready to use solution of selamectin. Stronghold is presented in a single use plastic tube for spot-on administration to dogs and cats. Each tube contains:

Stronghold 15 mg:	0.25 ml 6% selamectin
Stronghold 30 mg:	0.25 ml 12% selamectin
Stronghold 45 mg:	0.75 ml 6% selamectin
Stronghold 60 mg:	1 ml 6% selamectin
Stronghold 60 mg:	0.5 ml 12% selamectin
Stronghold 120 mg:	1 ml 12% selamectin
Stronghold 240 mg:	2 ml 12% selamectin
Stronghold 360 mg:	3 ml 12% selamectin respectively.

### Uses

#### *Dogs and Cats*

For the 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. Stronghold is also 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 for up to seven weeks of age.

For use 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.

For the treatment of ear mites (*Otodectes cynotis*).

For the prevention of heartworm disease caused by *Dirofilaria immitis* with monthly administration.

## Dogs

For the treatment of adult intestinal roundworms (*Toxocara canis*) in dogs. For the treatment of sarcoptic mange (caused by *Sarcoptes scabiei*) and biting lice infestations (caused by *Trichodectes canis*).

## Cats

For the treatment of adult roundworms (*Toxocara cati*) and adult intestinal hookworms (*Ancylostoma tubaeforme*). For the treatment of biting lice infestations (caused by *Felicola subrostratus*).

## Dosage and administration

Stronghold 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, only one application of the recommended 6 mg/kg dose should be administered at any one time.

Dogs (kg)	Pipette cap colour	mg of selamectin dispensed	Potency (mg/ml)	Volume (ml)
< 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 combination of pipettes
Cats (kg)	Pipette cap colour	mg of selamectin dispensed	Potency (mg/ml)	Volume (ml)
< 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 of pipettes	60	Appropriate combination of pipettes

## Fleas (cats and dogs)

For the treatment and prevention of flea infestations in dogs and cats, Stronghold 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 queens and bitches will aid prevention of infestations in the litter up to seven weeks of age.

For use as part of a treatment strategy for flea allergy dermatitis, Stronghold should be administered at monthly intervals.

### **Roundworm (cats and dogs)**

For the treatment of adult roundworm infections in dogs and cats, a single dose of Stronghold should be administered.

### **Hookworm (cats)**

For the treatment of adult hookworm infections in cats, a single dose of Stronghold should be administered.

### **Biting Lice (cats and dogs)**

For the treatment of biting lice infestations in cats and dogs, a single dose of Stronghold should be administered.

### **Sarcoptic Mange (dogs)**

For the complete elimination of sarcoptic mange mites in dogs, a single dose of Stronghold should be administered for two consecutive months.

### **Ear mites (cats)**

For the treatment of ear mites in cats, a single dose of Stronghold should be administered.

### **Ear mites (dogs)**

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

### **Heartworm (cats and dogs)**

For the prevention of heartworm disease in dogs and cats, Stronghold 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 last dose should be given within one month of the last exposure to mosquitoes.

### **Method and route of administration**

Spot-on use.

Remove the Stronghold pipette from its protective package. Holding the pipette upright, firmly depress the cap to puncture the applicator seal, then remove the cap. Part the hair

at the base of the animal's neck in front of the shoulder blades to expose a small area of skin. Apply the tip of the Stronghold pipette directly to the skin without massaging. Squeeze the pipette firmly to empty the contents in one spot. Avoid contact between Stronghold and fingers.

### Contra-indications, warnings, etc

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).

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

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 Stronghold.

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.

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

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

Avoid direct contact with treated animals until the application area 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 tubes should be disposed of immediately and not left within the sight or reach of children.

Use of Stronghold in cats has on rare occasions been associated with a mild, transient hair loss at the site of application. On very rare occasions transient focal irritation may also be observed. The hair loss and irritation are normally self-resolving, but symptomatic therapy may be applicable in some circumstances.

On rare occasions in cats and dogs, application of Stronghold may produce a local temporary clumping of the hair at the application site and/or the appearance of a small quantity of a white powder. This is normal and will disappear typically within 24 hours of administration and does not affect either the safety or efficacy of Stronghold.

Very rarely, as with other macrocyclic lactones, reversible neurological signs, including seizures, have been observed after use of Stronghold.

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

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

## Operator warnings

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

People with sensitive skin or known allergy to products of this type should handle Stronghold with caution.

Do not smoke, eat or drink while handling Stronghold.

## Pharmaceutical precautions

For animal treatment only.

Keep out of the sight and reach of children.

Do not store above 30°C. Store in the unopened foil package in a dry place.

Highly Flammable; keep away from heat, sparks, open flame or other sources of ignition.

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

Stronghold should not enter water courses as this may be dangerous for fish and other aquatic organisms. Containers and residual contents should be disposed of along with collected domestic refuse to avoid contamination of any water courses.

## Legal category

Legal category:POM-V

## Packaging quantities

Stronghold is available in packs of three tubes (all tube sizes), six tubes (all tube sizes except Stronghold 15 mg) and 15 tubes (Stronghold 15 mg only). Stronghold is provided in translucent polypropylene single-dose pipettes. Not all pack sizes may be marketed.

## Further information

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

Stronghold 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 beginning medication with Stronghold. 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 Stronghold has been administered monthly. Stronghold is not effective against adult *Dirofilaria immitis*,

If a dose is missed for heartworm prevention and a monthly interval between dosing is exceeded then immediate administration of the product and resumption of monthly dosing will minimise the opportunity of a development of adult heartworms. When replacing another heartworm preventative product in a heartworm disease prevention programme, the first dose of Stronghold must be given within a month of the last dose of the former medication.

Stronghold was administered at 10 times the recommended dose to cats and dogs and no undesirable effects were observed.

Stronghold can be used in breeding, pregnant and lactating cats and dogs; it was administered at 3 times the recommended dose to breeding male and female cats and dogs, including pregnant and lactating females nursing their litters and no undesirable effects were observed.

Stronghold was also administered at 5 times the recommended dose to ivermectin-sensitive collies, and no undesirable effects were observed.

Stronghold was also administered at 3 times the recommended dose to cats and dogs infected with adult heartworms and no undesirable effects were observed.

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

## Marketing Authorisation Number

EU/2/99/014/001-016

## Significant changes

### GTIN

**GTIN description:**15 mg x 3 tubes:

**GTIN:**05013457078497

**GTIN description:**15 mg x 15 tubes:

**GTIN:**05414736013435

**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

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