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## EPAR summary for the public

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# Stronghold Plus

selamectin / sarolaner

This is a summary of the European public assessment report (EPAR) for Stronghold Plus. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Stronghold Plus.

For practical information about using Stronghold Plus, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

## What is Stronghold Plus and what is it used for?

Stronghold Plus is a medicine used to treat mixed infestations with both ticks and other parasites that may be found on the skin or fur of cats, such as fleas, ear mites and lice and/or worms that live inside the body. The medicine can be used:

- to treat tick infestations
- to treat and prevent flea infestations. It can also be used as part of a treatment for flea allergy dermatitis (an allergic reaction to flea bites)
- to treat ear mites
- to treat biting lice infestations
- to treat adult roundworms and adult hookworms in the gut
- to prevent heartworm disease

Stronghold Plus must only be used when there is a need to treat ticks and one or more of the above parasites. Stronghold Plus contains two active substances, selamectin and sarolaner.

For further information, see the package leaflet.

## How is Stronghold Plus used?

Stronghold Plus is available as a spot-on solution in three different strengths and can only be obtained with a prescription. The contents of the pipette are squeezed onto the skin after parting the fur at the



base of the cat's neck in front of the shoulder blades. This small volume of liquid is absorbed through the skin and has an effect throughout the animal's body. The strength and number of pipettes used depends on the weight of the cat being treated.

Stronghold Plus kills fleas and some ticks within 24 hours and it continues to work for 5 weeks against fleas and 4 to 5 weeks against ticks (depending on the type).

For further information, see the package leaflet.

## **How does Stronghold Plus work?**

Selamectin and sarolaner are antiparasitic medicines.

Selamectin activates special proteins called 'chloride channels' on the surface of nerve and muscle cells of the parasite, allowing charged chloride particles to enter nerve cells and disrupting their normal electrical activity. This causes the paralysis or death of the parasites. Selamectin is effective against fleas, ear mites, biting lice, heartworms, roundworms and hookworms.

Sarolaner blocks the normal movement of charged chloride particles in and out of nerve cells, especially those associated with gamma-aminobutyric acid (GABA) and glutamate, two substances that convey messages between nerves (neurotransmitters). This results in uncontrolled activity of the nervous system and the paralysis and death of the parasites. Sarolaner is effective against ticks and fleas.

In order to be exposed to selamectin and sarolaner, fleas and ticks must commence feeding on the cat's blood.

## **What benefits of Stronghold Plus have been shown in studies?**

The effectiveness of Stronghold Plus was investigated in a field study in cats naturally infested with fleas. Cats were treated with Stronghold Plus monthly for 3 months or another antiparasitic medicine, containing imidacloprid and moxidectin. Stronghold Plus was as effective as the other medicine and reduced flea counts by more than 95%.

A second field study was conducted in cats naturally infested with ticks. Cats were treated with Stronghold Plus monthly for 3 months or another medicine, containing fipronil. Stronghold Plus was as effective as the other medicine and reduced tick counts by more than 90%.

Two laboratory studies with cats artificially infested with ear mites showed Stronghold Plus to reduce ear mites by more than 90% 30 days after a single treatment.

A laboratory study with cats infested with biting lice showed selamectin to eliminate biting lice for 42 days after treatment compared to placebo treated cats.

Two laboratory studies were conducted in cats with intestinal worms which showed Stronghold Plus to have more than 94% efficacy.

A laboratory study with cats artificially infected with heartworm showed Stronghold Plus to be effective for the prevention of heartworm disease.

## **What are the risks associated with Stronghold Plus?**

Use of the medicine may result in mild and short-lived itching at the application site.

The most common side effects with Stronghold Plus (which may affect up to 1 in 100 cats) are mild to moderate alopecia (hair loss) at the application site, erythema (reddening of the skin) and drooling

saliva.

Stronghold Plus must not be used in cats suffering from other diseases or in cats that are weak and underweight (for their age).

Because ticks must start feeding on the cat in order to be killed by the medicine, the risk of transmission of diseases that they may carry cannot be excluded.

For the full list of restrictions, see the package leaflet.

## **What are the precautions for the person who gives the medicine or comes into contact with the animal?**

Safety information has been included in the summary of product characteristics and the package leaflet for Stronghold Plus, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

Stronghold Plus is highly flammable and should be kept away from heat, sparks, any open flame or other sources of ignition.

Hands should be washed after use and any product in contact with the skin should be washed off immediately with soap and water.

People with sensitive skin or who are hypersensitive (allergic) to selamectin or sarolaner should handle Stronghold Plus with caution.

Stronghold Plus is harmful after swallowing. The medicine must be kept in its packaging until use, in order to prevent access by children. Used pipettes of the medicine must be disposed of immediately. If the product is accidentally swallowed by a person, the advice of a doctor should be sought immediately.

Treated animals must not be touched until the application area is dry. Children must not be allowed to play with treated cats for 4 hours after treatment. It is recommended to treat cats in the evening. On the day of treatment, treated cats must not be allowed to sleep in the same bed as their owner, especially children.

In case of skin or eye contact the affected area should be rinsed immediately with water.

## **Why is Stronghold Plus approved?**

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Stronghold Plus's benefits are greater than its risks and recommended that it be approved for use in the EU.

## **Other information about Stronghold Plus**

The European Commission granted a marketing authorisation valid throughout the EU for Stronghold Plus on 9 February 2017.

The full EPAR for Stronghold Plus can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Veterinary\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Veterinary_medicines/European_public_assessment_reports). For more information about treatment with Stronghold Plus, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in December 2016.