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EPAR summary for the public

Stronghold

Selamectin

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use. This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Stronghold?

Stronghold is an antiparasitic medicine that contains the active substance selamectin. It is available as a spot-on solution in 2 different concentrations (6% and 12%) and in tubes of various strengths (15, 30, 45, 60, 120, 240 and 360 mg). The concentration and the strength to use depends on the weight and species of the animal being treated.

What is Stronghold used for?

Stronghold is used to treat and prevent infestations with parasites that live on the skin or in the fur of cats and dogs, such as fleas and mites, as well as treating worm parasites that live inside the body. It is used in the following ways:

- to treat and prevent flea infestations in cats and dogs, by killing adult fleas, their larvae and their eggs on the animal, and in the litters of pregnant or nursing cats or dogs. It can also be used as part of a treatment for flea allergy dermatitis (skin inflammation),
- to prevent heartworm disease in cats and dogs,
- to treat ear mites in cats and dogs,
- to treat adult intestinal roundworms and intestinal hookworms in cats,
- to treat adult intestinal roundworms in dogs,

- to treat biting lice in cats and dogs,
- to treat sarcoptic mange (scabies) in dogs.

The contents of the tube are squeezed onto the skin after parting the fur between the shoulder blades. This small volume of liquid is absorbed through the skin and has an effect throughout the animal's body. The strength used and the number of administrations depend on the weight and species of the animal being treated, and the type of parasite. The package leaflet contains detailed information on dosage and duration of treatment.

How does Stronghold work?

Stronghold contains selamectin, which is an antiparasitic medicine that belongs to the 'avermectin' class. 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.

How has Stronghold been studied?

The effectiveness of Stronghold against the specified parasites was investigated in laboratory studies in cats and dogs. The effectiveness was then confirmed in field studies in cats and dogs by looking at the number of live parasites at various times after treatment.

What benefit has Stronghold shown during the studies?

Stronghold treatment was found to be effective after a single administration or repeated treatments at monthly intervals, depending on the type of infestation it was being used to treat or prevent.

In field studies, it reduced the flea comb counts by up to 98% in cats and 99% in dogs 90 days after treatment, as well as preventing flea eggs from hatching, and killing and preventing the development of flea larvae. Field studies also showed that Stronghold was 100% effective in preventing heartworm disease in dogs and cats. It is also effective in treating ear mites in cats and dogs. In the treatment of sarcoptic mange in dogs, two treatments given 30 days apart were required to completely eliminate the mites in dogs. Stronghold was also effective in the treatment of adult intestinal hookworms in cats, adult intestinal roundworms in cats and dogs, and biting lice in dogs and cats.

Shampooing or soaking the animal two hours or more after treatment did not affect the medicine's effectiveness.

What is the risk associated with Stronghold?

Stronghold causes temporary alopecia (hair loss) at the application site in less than 1 in 1,000 cats.

Stronghold may produce clumping of the hair at the application site or the appearance of a small quantity of a white powder in less than 1 in 1,000 cats. This does not affect the safety or effectiveness of the medicine.

Stronghold must not be used in animals under six weeks of age. It must also not be used in cats that are suffering from another disease or that are weakened and underweight for their size and age.

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

Stronghold is highly flammable and should be kept away from heat, sparks, any open flame or other sources of ignition. The user must not smoke, eat or drink while handling Stronghold. Hands should be washed after use and any product in contact with the skin should be washed off immediately with soap and water. If Stronghold comes into contact with the eyes, they should be flushed immediately with water and medical attention sought.

Treated animals must not be touched until the application area is dry. On the day of treatment, children must not handle treated animals and the animals should not sleep with their owners, especially children. Used applicators should be disposed of immediately and not left within sight or reach of children. People with sensitive skin or known allergy to products of this type should handle Stronghold with caution.

Why has Stronghold been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) agreed that the benefits of Stronghold exceed the risks for the approved indications and recommended that Stronghold be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Stronghold:

The European Commission granted a marketing authorisation valid throughout the European Union for Stronghold on 25 November 1999. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in January 2015.