



EUROPEAN MEDICINES AGENCY
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EPAR summary for the public

Simparica

Sarolaner

This is a summary of the European public assessment report (EPAR) for Simparica. 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 Simparica.

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

What is Simparica and what is it used for?

Simparica is a veterinary medicine used to treat infestations with ticks and fleas, demodectic and sarcoptic mange (skin infestations caused by two different types of mites) and ear mite infestations in dogs. After Simparica is given its activity against ticks and fleas lasts for at least 5 weeks. Simparica can be used as part of the management of flea allergy dermatitis (an allergic reaction to flea bites). It contains the active substance sarolaner.

For further information, see the package leaflet.

How is Simparica used?

Simparica is available as chewable tablets (5, 10, 20, 40, 80 and 120 mg) and can only be obtained with a prescription. The appropriate strength tablet(s) should be used according to the dog's weight.

For treatment of tick and flea infestations Simparica should be given once every month throughout the flea and/or tick season for optimal control.

For treatment of sarcoptic mange, Simparica is given monthly for two consecutive months.

For treatment of demodectic mange Simparica should be given once a month for at least three months. Treatment should be continued until skin scrapings are negative on at least two consecutive occasions one month apart. As other conditions contribute to demodectic mange, any underlying diseases should also be treated.



For treatment of ear mite infestations a single dose should be given.

For further information, see the package leaflet.

How does Simparica work?

The active substance in Simparica, sarolaner acts as an 'ectoparasiticide'. This means that it kills parasites that live on the skin or in the fur of animals, such as fleas, ticks and mites. In order to be exposed to the active substance, fleas and ticks must attach to the skin and commence feeding on the dog's blood. Sarolaner kills these parasites that have ingested the dog's blood by acting on their nervous system. It blocks the normal movement of charged chloride particles (ions) 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 kills fleas before they can lay eggs and so helps to reduce contamination of the dog's environment.

What benefits of Simparica have been shown in studies?

The effectiveness of Simparica against fleas was investigated in a field study in dogs infested with at least five live fleas. 189 dogs were treated with Simparica for three months whilst 96 dogs were given another medicine, spinosad. Simparica was as effective as spinosad in reducing flea counts for up to 90 days after treatment.

A field study was conducted in dogs infested with at least three live attached ticks. 122 dogs were treated with Simparica for three months whilst 59 dogs were treated with another medicine, fipronil, against ticks. Simparica was as effective as fipronil in reducing tick counts for up to 90 days after treatment.

Another study involved dogs infested with sarcoptic mange. 53 dogs were treated with Simparica for two months whilst 26 dogs were given a medicine containing moxidectin and imidacloprid. Simparica was as effective as moxidectin and imidacloprid in eliminating live mites in skin scrapings.

In a study involving dogs with ear mite infestation, 283 dogs were treated with Simparica and 131 dogs received moxidectin/imidacloprid (a spot-on mite treatment). Dogs with live mites on day 30 after initial treatment received a second treatment. For Simparica the percentage of dogs with no live ear mites present was 91% at day 30 increasing to 99% on day 60, following two treatments. Simparica was as effective as moxidectin/imidacloprid.

In a study with 98 dogs with demodectic mange, 63 dogs were treated with Simparica monthly for up to six months and 35 dogs received moxidectin/imidacloprid. Simparica was as effective as moxidectin/imidacloprid and the percentage of Simparica-treated dogs with no live mites was 15%, 69%, 93%, 94%, 100% and 100% on days 30, 60, 90, 120, 150 and 180, respectively.

What are the risks associated with Simparica?

Side effects with Simparica are not common. However, the following side effects are seen in less than 1 dog in 10,000: mild and short-lived vomiting and diarrhoea as well as tremor (shaking), ataxia (inability to coordinate body movements) or convulsions. These signs usually resolve without treatment.

Because fleas and ticks must start feeding on the dog in order to be killed by the medicine, the risk of transmission of diseases with which they may be infected cannot be excluded.

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 Simparica, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

The tablets should be kept in the original package until use in order to prevent children directly accessing the medicine.

Hands should be washed after handling the medicine. If the product is accidentally swallowed by a person, the advice of a doctor should be sought immediately.

Why is Simparica approved?

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

Other information about Simparica

The European Commission granted a marketing authorisation valid throughout the EU for Simparica on 6 November 2015.

The full EPAR for Simparica 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%20medicines/European%20public%20assessment%20reports). For more information about treatment with Simparica, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in September 2017.