



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Simparica Trio (sarolaner / moxidectin / pyrantel)

An overview of Simparica Trio and why it is authorised in the EU

### What is Simparica Trio and what is it used for?

Simparica Trio is a veterinary medicine used to treat dogs with flea or tick infestations and roundworm or hookworm infections in the gut. At the same time, Simparica Trio is used to prevent heartworm and lungworm disease (both caused by blood worms that infect the heart and blood vessels supplying the lungs). It can also be used as part of a treatment for flea allergy dermatitis (an allergic reaction to flea bites). Simparica Trio contains the active substances sarolaner, moxidectin and pyrantel.

### How is Simparica Trio used?

Simparica Trio is available as chewable tablets and can only be obtained with a prescription. The appropriate tablet strength should be used according to the dog's weight. Simparica Trio must only be used when there is a need to treat both fleas or ticks and worms in the gut.

For gut worms only a single treatment is required. For flea or tick infestations, one treatment with Simparica Trio is effective for up to 5 weeks. Further flea or tick treatment should be continued using a different veterinary medicine with a narrower range of action.

To prevent lungworm and heartworm disease for one month, a single treatment is required. In areas where lungworm and heartworm are present, treatments are required at monthly intervals.

For more information about using Simparica Trio, see the package leaflet or contact your veterinarian or pharmacist.

### How does Simparica Trio work?

Simparica contains three active substances: sarolaner, moxidectin and pyrantel. Sarolaner acts as an 'ectoparasiticide'. This means that it kills parasites present on the skin or in the fur of animals, such as fleas and ticks. 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 signals between nerves (neurotransmitters). This results in

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uncontrolled activity of the nervous system and thus 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.

Moxidectin kills parasites present inside the body of animals, such as roundworms, hookworms, lungworm and heartworm. Moxidectin causes paralysis and death of these parasites by interfering in a different way to sarolaner with the flow of chloride ions in nerve cells associated with GABA and glutamate.

Pyrantel also kills roundworms and hookworms present in the gut but acts differently to moxidectin. It acts by blocking signals, normally associated with the neurotransmitter acetylcholine, from their nerves to their muscles, causing sudden contraction followed by paralysis and death.

## **What benefits of Simparica Trio have been shown in studies?**

### **Fleas**

In a field study in dogs infested with at least 5 live fleas, 297 dogs were treated with Simparica Trio and 164 dogs with afoxolaner and milbemycin oxime (an authorised treatment for fleas and ticks). The study showed Simparica Trio to be comparable to the comparator medicine as measured by flea counts on day 14 and 30 after treatment.

### **Ticks**

In a further field study in dogs infested with at least 3 live ticks, 189 dogs were treated with Simparica Trio and 91 dogs with afoxolaner and milbemycin oxime. The study showed Simparica Trio to be comparable to the comparator medicine as measured by the percentage reduction in live tick counts on day 7, 14, 21 and 30 after treatment.

### **Roundworms and hookworms**

In a field study involving dogs infected with roundworms or hookworms, 194 dogs were treated with Simparica Trio and 97 dogs with afoxolaner and milbemycin oxime. Effectiveness, based on faecal egg counts on day 7 after treatment, for dogs treated with Simparica Trio was comparable to the comparator medicine.

### **Lungworms**

In a field study involving 622 dogs in an area of Denmark and Italy known to be affected by lungworm disease, dogs treated with Simparica Trio every 30 days until day 270 did not test positive for lungworm until day 300 after first treatment and therefore the effectiveness was 100% with some dogs testing positive in the control group which was given a dummy treatment.

### **Heartworms**

Four field studies were conducted. In a US study of 410 dogs in an area affected by heartworm disease, dogs treated with Simparica Trio every 30 days until day 300 showed 100% effectiveness based on blood tests at days 120, 240 and 330 after first treatment. Two studies conducted in Australia and one in Japan that followed a similar design to the US study also showed 100% effectiveness against naturally occurring heartworm infection.

## **What are the risks associated with Simparica Trio?**

There are no known side effects. For the 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 Simparica Trio, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

The tablets should be kept in the original packaging 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 Trio authorised in the EU?**

The European Medicines Agency decided that Simparica Trio's benefits are greater than its risks and it can be authorised for use in the EU.

## **Other information about Simparica Trio**

Simparica Trio received a marketing authorisation valid throughout the EU on 17 September 2019.

Further information on Simparica Trio can be found on the Agency's website: [ema.europa.eu/Find/medicines/veterinary/EPAR/simparica-trio](http://ema.europa.eu/Find/medicines/veterinary/EPAR/simparica-trio).

This overview was last updated in July 2019.