



EUROPEAN MEDICINES AGENCY  
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## Nexgard Spectra (*afoxolaner/milbemycin oxime*)

An overview of Nexgard Spectra and why it is authorised in the EU

### What is Nexgard Spectra and what is it used for?

Nexgard Spectra is a veterinary medicine used to treat infestations with fleas, ticks, as well as demodectic and sarcoptic mange (skin infestations caused by two different types of mites) in dogs when prevention of heartworm disease (caused by a roundworm that infects the heart and blood vessels and is transmitted by mosquitoes), angiostrongylosis (caused by lungworms) and/or treatment of gut worms (hookworms, roundworms and whipworm) is also required.

Nexgard Spectra contains the active substances afoxolaner and milbemycin oxime.

### How is Nexgard Spectra used?

Nexgard Spectra is available as chewable tablets in five different strengths for use in dogs of different weights. It can only be obtained with a prescription. The appropriate strength of tablets should be used according to the dog's weight.

Treatment for fleas and ticks should be repeated at monthly intervals during the flea or tick seasons. For demodectic mange treatment should be repeated monthly until the mange is successfully treated (as confirmed by two negative skin scrapings one month apart) whereas for sarcoptic mange treatment is given monthly for two months, or longer if treatment is unsuccessful as indicated by clinical signs and skin scrapings. For prevention of heartworm disease, treatment is given monthly during the mosquito season. For prevention of angiostrongylosis, in areas where infection regularly occurs, monthly treatment is given.

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

### How does Nexgard Spectra work?

The active substances in Nexgard Spectra work by interfering with the way that signals are passed between nerve cells (neurotransmission) in the nervous system of parasites, resulting in paralysis and death of the parasitic organism.



Afoxolaner acts as an 'ectoparasiticide'. This means that it kills parasites that live on or in the skin or in the fur of animals, such as fleas, ticks and mites. In order to be exposed to afoxolaner, fleas and ticks must attach to the skin and commence feeding on the dog's blood. Afoxolaner kills fleas before they can lay eggs and so helps to reduce contamination of the dogs' environment.

Milbemycin oxime acts as an 'endoparasiticide'. This means that it kills parasites like worms that live inside the body of animals.

## **What benefits of Nexgard Spectra have been shown in studies?**

The effectiveness of Nexgard Spectra was investigated in both laboratory and field studies.

For ectoparasites, there were three field studies. The first involved 324 dogs with flea and/or tick infestations that were given a single treatment with Nexgard Spectra or a spot-on medicine containing another active substance, pyriproxyfen, that controls fleas and ticks. The study showed that Nexgard Spectra was effective in treating flea and tick infestations in dogs for up to 30 days after treatment. Nexgard Spectra reduced the number of fleas and ticks by at least 95% and was at least as effective as pyriproxyfen.

A second field study involved 19 dogs with demodectic mange which were treated with Nexgard Spectra monthly on three occasions. Nexgard Spectra reduced the number of live mites by 96% 56 days after starting treatment and by 98% 84 days after starting treatment.

A third field study involved 27 dogs with sarcoptic mange which were treated with Nexgard Spectra monthly for two months. Nexgard Spectra reduced the number of live mites by 99% 28 days after starting treatment and by 100% 56 days after starting treatment.

For gut worms, a field study involved 408 dogs with infections that were given either a single treatment with Nexgard Spectra or a medicine containing milbemycin oxime and praziquantel (another medicine for worms). The study showed that Nexgard Spectra was effective in reducing gut worms and was at least as effective as the milbemycin oxime and praziquantel.

For heartworm, 84 dogs in Japan and 320 dogs in the USA, none of which had heartworm before the treatment started, showed that Nexgard Spectra prevented heartworm infection for six months after treatment.

For angiostrongylosis, a laboratory study involved 20 dogs artificially infected with lungworm larvae 7 times at 2-week intervals. Ten dogs were given Nexgard Spectra and the other 10 were untreated. Nexgard Spectra reduced worm counts by 95% on the basis of post-mortem examination at 90-92 days after treatment.

## **What are the risks associated with Nexgard Spectra?**

The most common side effects (affecting in between 1 to 10 animals in 1,000 animals) were vomiting, diarrhoea, lack of energy, decreased appetite, and itching, which generally were short-lived and resolved spontaneously.

Because parasites must start feeding on the dog in order to be killed by the medicine, there may be a risk of transmission of diseases with which they may be infected.

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

Tablets should be kept in the blister packs until required, and the blisters should be kept in the carton.

In the case of accidental ingestion, particularly in the case of children, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

People handling the medicine should wash their hands after handling the product.

## **Why is Nexgard Spectra authorised in the EU?**

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

## **Other information about Nexgard Spectra**

Nexgard Spectra received a marketing authorisation valid throughout the EU on 15 January 2015.

Further information on Nexgard Spectra can be found on the Agency's website:  
[ema.europa.eu/medicines/veterinary/EPARs/Nexgard-Spectra](http://ema.europa.eu/medicines/veterinary/EPARs/Nexgard-Spectra).

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