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EPAR summary for the public

Nexgard Spectra
afoxolaner / milbemycin oxime

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

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

What is Nexgard Spectra and what is it used for?

Nexgard Spectra is a veterinary medicine used to treat flea and tick infestations 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.

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. Treatment should be repeated at monthly intervals during the flea or tick seasons. For prevention of heartworm disease, treatment is given monthly during the mosquito season. For angiostrongylosis, in areas where infection regularly occurs, monthly treatment is given. The appropriate strength of tablets should be used according to the dog’s weight.

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 the skin or in the fur of animals, such as fleas and ticks. 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 a field study 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.

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 fleas and ticks must start feeding on the dog in order to be killed by the medicine, the risk of transmission of diseases from an infected tick to a dog cannot be excluded.

**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 approved?

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

Other information about Nexgard Spectra:

The European Commission granted a marketing authorisation valid throughout the EU, for Nexgard Spectra on 15/01/2015.

The full EPAR for Nexgard Spectra can be found on the Agency’s website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Nexgard Spectra animal owners of keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in March 2017.