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 worm that infects the heart and blood vessels and is transmitted by mosquitoes), lungworm disease, eye worm 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; Nexgard Spectra can be used as part of the seasonal treatment of fleas and ticks in dogs infected with gut worms. A single dose of Nexgard Spectra is given to treat gut worms. After which, further flea and tick treatment should be continued with a monovalent product containing a single active substance. 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 based on clinical signs and skin scrapings. For prevention of heartworm disease, treatment is given monthly during the mosquito season. For prevention of lungworm disease, in areas where infection regularly occurs, and for prevention of eye worm, 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.

Flea and tick infestations

In a field study, 324 dogs with flea and/or tick infestations were given a single treatment with Nexgard
Spectra or a spot-on medicine containing another active substance, pyriprole, 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 pyriprole.

Demodectic mange

In a field study, 19 dogs with demodectic mange 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.

Sarcoptic mange

In a field study, 27 dogs with sarcoptic mange 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.

Gut worms

In a field study, 408 dogs with gut worm infections 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.

Heartworm

Field studies involving 84 dogs in Japan and 320 dogs in the USA, none of which had heartworm before
the treatment started, showed that Nexgard Spectra given monthly for six months prevented
heartworm infection.

Lungworm

A laboratory study involved 20 dogs artificially infected with lungworm larvae. Ten dogs were given
Nexgard Spectra and the other 10 were untreated. Nexgard Spectra reduced worm counts by 95% at
90-92 days after treatment.

Eye worm

In a field study conducted at sites in Europe where cases of eye worm are known to exist, dogs were
confirmed free of eye worm at the start of the study. Thirty seven dogs were treated with Nexgard Spectra and 42 dogs were treated with afoxolaner alone, which has no action against eye worm. Treatments were given monthly for 6 months. All the dogs treated with Nexgard Spectra were free of eye worm at day 180 compared to 43% in the afoxolaner-treated group.

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

The most common side effects (affecting inbetween 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, 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.

This overview was last updated in July 2019.