



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/783550/2013
EMA/V/C/002729

NexGard (*afoxolaner*)

An overview of NexGard and why it is authorised in the EU

What is NexGard and what is it used for?

NexGard is a medicine used to treat infestations with fleas and ticks, as well as demodectic and sarcoptic mange (skin infestations caused by two different types of mites) in dogs. It may be used as part of the management of flea allergy dermatitis (an allergic reaction to flea bites).

NexGard contains the active substance afoxolaner.

How is NexGard used?

NexGard is available as chewable tablets in four different strengths for use in dogs of different weights. It can only be obtained with a prescription. NexGard is given as a tablet of the appropriate strength for the dog's bodyweight.

NexGard kills fleas within 8 hours and ticks within 48 hours. After being given, its actions last for at least 5 weeks against fleas and up to one month against ticks. Treatment should be repeated at monthly intervals during the flea or tick seasons, monthly for demodectic mange until the mange is successfully treated (as confirmed by two negative skin scrapings one month apart) and monthly for two months for sarcoptic mange, or longer if treatment is unsuccessful as indicated by clinical signs and skin scrapings.

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

How does NexGard work?

The active substance in NexGard, 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 for the active substance to have an effect, fleas and ticks must attach to the skin and commence feeding on the dog's blood.

Afoxolaner kills parasites by causing an over-stimulation of 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), a substance which conveys messages between nerves (neurotransmitter). This results in uncontrolled activity of the nervous system and the paralysis and



death of fleas, ticks and mites. Afoxolaner kills fleas before they can lay eggs and so helps to reduce contamination of the dogs' environment.

What benefits of NexGard have been shown in studies?

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

In an EU field study involving 146 dogs with flea and/or tick infestations, a single treatment with NexGard was effective in treating flea and tick infestations in dogs for up to 30 days after treatment. NexGard reduced the number of fleas and ticks by at least 98% and was at least as effective as a spot-on medicine containing pyriprole (another medicine against fleas and ticks).

A second EU field study involved 31 dogs with demodectic mange which were treated monthly on 3 occasions with NexGard. NexGard reduced the number of live mites by 97% 56 days after starting treatment and by 98% 84 days after starting treatment.

A third EU field study involved 38 dogs with sarcoptic mange which were treated monthly for two months with NexGard. NexGard reduced the number of live mites by 96% 28 days after starting treatment and by 100% 56 days after starting treatment.

What are the risks associated with NexGard?

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?

Only one chewable tablet at a time should be removed from the blister to prevent children from accessing the product. The blister with the remaining chewable tablets should be returned into the carton.

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

Why is NexGard authorised in the EU?

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

Other information about NexGard

NexGard received a marketing authorisation valid throughout the EU on 11 February 2014.

Further information on NexGard can be found on the Agency's website:
ema.europa.eu/medicines/veterinary/EPAR/NexGard.

This overview was last updated in September 2018.