



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/628709/2020  
EMA/V/C/005094

## NexGard Combo (*esafoxolaner / eprinomectin / praziquantel*)

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

### What is NexGard Combo and what is it used for?

NexGard Combo is an antiparasitic veterinary medicine used to treat mixed infections with external parasites (fleas, ticks or mites) and internal parasites (tapeworm and roundworms) in cats.

The medicine should only be used in confirmed mixed infections or if cats are at significant risk of mixed infection with external parasites and roundworms and need treatment against tapeworm at the same time. If there is no risk of co-infestation, a narrower spectrum antiparasitic medicine should be considered.

For external parasites, an application of NexGard Combo can treat flea and tick infestation for one month. It can also be used to treat infestations with ear or skin mites and as part of the management of flea allergy dermatitis (an allergic skin reaction to flea bites).

For internal parasites, NexGard Combo can be used to treat infections with tapeworms and roundworms/hookworms in the gut as well as lungworms and a roundworm that infects the bladder. NexGard Combo can also be used to prevent heartworm disease for one month per application.

NexGard Combo contains the active substances esafoxolaner, eprinomectin and praziquantel.

### How is NexGard Combo used?

NexGard Combo can only be obtained with a prescription. The medicine is available as a spot-on solution in applicators of two different volumes. The volume depends on the cat's bodyweight. The content of the applicator is applied to the cat's skin in a single spot in the middle of the neck where the cat cannot lick it off. Repeated treatments should be restricted to limited individual situations, with a minimum treatment interval of 4 weeks.

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

### How does NexGard Combo work?

The active substances in NexGard Combo act in different ways to kill external and internal parasites.



Esafoxolaner is an ectoparasiticide, which means that it kills external parasites that live on or in the skin, in the fur or in the ear of the cat. It interferes with the way signals pass between the parasite's nerve cells (neurotransmission), resulting in uncontrolled activity of the parasite's nervous system and death. Fleas and ticks are killed within 24 and 48 hours after treatment, respectively. Esafoxolaner kills fleas before egg production and therefore prevents household contamination.

Praziquantel and eprinomectin are endoparasiticides, which means they kill parasites that live inside the cat's body. Praziquantel damages the cell membranes of tapeworms, leading to the death of the parasite. Eprinomectin interferes with nerve and muscle cells of roundworms, leading to the paralysis and death of the parasite.

## What benefits of NexGard Combo have been shown in studies?

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

### Ectoparasites

In one field study in several EU countries, 557 cats with flea and/or tick infestations were given a single treatment with NexGard Combo or a comparator spot-on medicine containing different active substances (fipronil and (S)-methoprene). The study showed that NexGard Combo was effective in reducing the number of **fleas** in cats with flea infestations by at least 95% for up to 30 days after treatment; this treatment was at least as effective as the comparator product. No clear conclusion regarding the effectiveness of NexGard Combo against **ticks** could be drawn from this study, but adequate effectiveness of NexGard Combo against the tick species *Ixodes ricinus* was shown in dose-confirmation studies.

In another field study in 2 European countries, the effectiveness of a single dose of NexGard Combo was compared with placebo (a dummy treatment) against **ear mites** in 115 naturally infested cats. The study showed that NexGard Combo was effective in reducing the number of ear mites by at least 90%.

In a laboratory study with naturally and artificially infested cats, the efficacy of NexGard Combo against **skin mites** (notoedric mange) was compared to a placebo treatment at different time points. At each time point, the efficacy of NexGard Combo was 100%.

### Endoparasites

In addition to a number of laboratory studies, a study on the effectiveness of the active substances eprinomectin and praziquantel was also already carried out with the authorised medicine Broadline. This study showed that the active substances are almost 100% effective against **tapeworms and intestinal roundworms** (*Toxocara cati*, *Ancylostoma spp*, *Toxascaris leonina*).

Echinococcosis caused by **Echinococcus multilocularis tapeworms** is a risk for humans and therefore medicines against these parasites must be 100% effective. Laboratory studies using artificially infected cats showed that NexGard Combo was effective at treating infections with *E. multilocularis*. Laboratory data previously submitted for Broadline (which also contains praziquantel, the active substance against this tapeworm) also showed 100% effectiveness.

Laboratory studies in artificially infected cats confirmed the effectiveness of NexGard Combo in preventing **heartworm disease** caused by *Dirofilaria immitis* for one month.

The effectiveness of NexGard Combo against different developmental stages of **feline lungworm** (*Aelurostrongylus abstrusus*) was demonstrated in a laboratory study. The effectiveness was further supported by studies previously carried out with the authorised medicine Broadline.

A study on the effectiveness of the active substances eprinomectin and praziquantel was previously carried out with the authorised medicine Broadline and showed that the active substances are more than 90% effective against another species of **feline lungworm** (*Troglostrongylus brevior*). Laboratory studies previously carried out with Broadline have also shown that the active substances are 100% effective against **vesical roundworms** (*Capillaria plica*) that affect the bladder.

## **What are the risks of NexGard Combo?**

The most frequent side effects with NexGard Combo (which may affect between 1 and 10 animals in 1,000) are excessive salivation, diarrhoea, skin reactions at the application site (hair loss, itching), loss of appetite, lethargy and vomiting. These reactions occur shortly after application and are mostly mild, of short duration and self-limiting.

For the full list of side effects of NexGard Combo, 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 NexGard Combo, including the precautions to be followed by healthcare professionals and animal owners or keepers.

People who are hypersensitive (allergic) to esafoxolaner, eprinomectin or praziquantel should avoid contact with NexGard Combo.

The person who applies the medicine should not smoke, eat or drink during application and should avoid the medicine touching their fingers. They should wash their hands after handling the product.

People should not touch the animal at the site of application until the treated area is no longer noticeable. Children should not be allowed to play with treated animals until the application site is no longer noticeable and it is recommended that recently treated animals do not sleep with owners, especially children. It is recommended to treat animals in the evening to reduce contact with people after treatment.

In case of skin or eye contact, immediately rinse the affected area with water and remove any contaminated clothes. Seek medical advice and show the package leaflet or the label to the physician.

People with known hypersensitivity to any of the ingredients should avoid contact with the product.

Pregnant women should wear gloves when applying the medicine to avoid direct contact with it.

## **Why is NexGard Combo authorised in the EU?**

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

## **Other information about NexGard Combo**

NexGard Combo received a marketing authorisation valid throughout the EU on 06 January 2021.

Further information on NexGard Combo can be found on the Agency's website:

[ema.europa.eu/medicines/veterinary/EPAR/nexgard-combo](https://ema.europa.eu/medicines/veterinary/EPAR/nexgard-combo).

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 10-2021.