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NexGard chewable tablets for dogs (Northern Ireland)

NexGard 11 mg chewable tablets for dogs 2–4 kg

NexGard 28 mg chewable tablets for dogs > 4–10 kg

NexGard 68 mg chewable tablets for dogs > 10–25 kg

NexGard 136 mg chewable tablets for dogs > 25–50 kg

Species: Dogs

Therapeutic indication:Pharmaceuticals: Ectoparasiticides: For dogs

Active ingredient: Afoxolaner

Product: NexGard Chewable Tablets for Dogs

Product index: NexGard

Incorporating:

Qualitative and quantitative composition

Active substance:

NexGard	**Afo**
Chewable tablets for dogs 2-4 kg	11.3
Chewable tablets for dogs > 4-10 kg	28.3
Chewable tablets for dogs > 10-25 kg	68.(
Chewable tablets for dogs > 25-50 kg	136

Excipients:

NOAH Compendium

Qualitative composition of excipients and other constituents

Maize starch

Soy protein fines

Beef braised flavouring

Povidone (E1201)

Macrogol 400

Macrogol 4000

Macrogol 15 hydroxystearate

Glycerol (E422)

Triglycerides, medium-chain

Mottled red to reddish brown, circular shaped chewable tablets (for dogs 2–4 kg) or rectangular shaped chewable tablets (for dogs > 4–10 kg, for dogs > 10–25 kg and for dogs > 25–50 kg).

Pharmaceutical form

See QUALITATIVE AND QUANTITATIVE COMPOSITION section

Clinical particulars

Target species

Dogs

Indications for use for each target species

Treatment of flea infestation in dogs (*Ctenocephalides felis* and *C. canis*). The veterinary medicinal product provides immediate and persistent killing activity for at least 5 weeks.

For reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for 30 days. The effect is indirect due to the activity of the veterinary medicinal product against the vector.

The product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

Treatment of tick infestation in dogs (*Dermacentor reticulatus, Ixodes ricinus, Ixodes hexagonus, Rhipicephalus sanguineus, Hyalomma marginatum*). The veterinary medicinal product provides immediate and persistent killing activity for one month.

For reduction of the risk of infection with *Babesia canis canis* via transmission by *Dermacentor reticulatus* for 28 days. The effect is indirect due to the activity of the veterinary medicinal product against the vector.

Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.

Treatment of demodicosis (caused by *Demodex canis*).

Treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*).

Treatment of ear mite infestations (caused by *Otodectes cynotis*).

Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Special warnings

Parasites need to start feeding on the host to become exposed to afoxolaner; therefore the risk of the transmission of parasite borne diseases cannot be excluded.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and burden, or of the risk of infestation based on its epidemiological features, for each individual animal.

The possibility that other animals in the same household can be a source of re-infestation with fleas, ticks or mites should be considered, and these should be treated as necessary with an appropriate product.

Special precautions for use

Special precautions for safe use in the target species:

In the absence of available data, treatment of puppies less than 8 weeks of age and/or dogs less than 2 kg bodyweight should be based on a benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To prevent children from getting access to the veterinary medicinal product, remove only one chewable tablet at a time from the blister. Return the blister with the remaining chewable tablets into the carton. In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.

Wash hands after handling the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

Adverse events

Dogs:

Very rare (< 1 animal / 10 000 animals treated, including isolated reports):	Digestive tract disorders1
	Lethargy2, anorexia2
	Pruritus2
	Neurological disorders (c

1 Mild.

2 Mostly self-limiting and of short duration.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used in pregnant and lactating dogs.

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects.

Fertility:

Can be used in breeding females.

The safety of the veterinary medicinal product has not been established in breeding males. In breeding males, use only according to the benefit-risk assessment by the responsible veterinarian.

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects, or any adverse reactions on the reproductive capacity of males.

Interaction with other medicinal products and other forms of interaction

None known.

Administration routes and dosage

Oral use.

Dosage:

The veterinary medicinal product should be administered at a dose of 2.7 to 7 mg/kg bodyweight of afoxolaner in accordance with the following table:

Bodyweight of dog (kg)	Strength and number of chewable tablets to be administered
2 - 4	1 x NexGard 11 mg
>4 - 10	1 x NexGard 28 mg
>10 - 25	1 x NexGard 68 mg
>25 - 50	1 x NexGard 136 mg

For dogs above 50 kg bodyweight, use an appropriate combination of chewable tablets of different/same strengths.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The chewable tablets should not be divided. Underdosing could result in ineffective use and may favour resistance development.

Method of administration:

The tablets are chewable and palatable to most dogs. If the dog does not accept the tablets directly they may be administered with food.

Treatment schedule:

Treatment of flea and tick infestations:

Monthly intervals throughout the flea and/or tick seasons, based on local epidemiological situations and the animal's lifestyle.

Treatment of demodicosis (caused by Demodex canis):

Monthly administration of the veterinary medicinal product is efficacious and leads to a marked improvement of clinical signs. Treatment should be continued until two negative skin scrapings are obtained one month apart. Severe cases may require prolonged monthly treatments. As demodicosis is a multi-factorial disease, where possible, it is advisable to also treat any underlying disease appropriately.

Treatment of sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*):

Monthly administration of the veterinary medicinal product for two consecutive months. Further monthly administration may be required based on clinical assessment and skin scrapings.

Treatment of ear mite infestations (caused by *Otodectes cynotis*):

A single dose of the veterinary medicinal product should be administered. A further veterinary examination one month after the initial treatment is recommended as some animals may require a second treatment.

Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions were observed in healthy Beagle puppies over 8 weeks of age when treated with 5 times the maximum dose repeated 6 times at intervals of 2 to 4 weeks.

Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

Withdrawal periods

Not applicable.

Pharmacodynamics

Afoxolaner is an insecticide and acaricide belonging to the isoxazoline family. Afoxolaner acts at ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarines. The selective toxicity of afoxolaner between insect/acarines and mammals may be inferred by the differential sensitivity of the insect/acarines' GABA receptors versus mammalian receptors.

Afoxolaner is active against adult fleas as well as several tick species such as *Dermacentor reticulatus* and *D. variabilis, Ixodes ricinus, Ixodes hexagonus* and *I. scapularis, Rhipicephalus sanguineus, Amblyomma americanum, Haemaphysalis longicornis*, and *Hyalomma marginatum*.

The veterinary medicinal product kills fleas within 8 hours and ticks within 48 hours.

The veterinary medicinal product kills fleas before egg production and therefore prevents household contamination.

Pharmaceutical particulars

Major incompatibilities

Not applicable.

Shelf life

Shelf life of the product as packaged for sale: 3 years

Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

Nature and composition of immediate packaging

The veterinary medicinal product is individually packaged in thermoformed laminated PVC blisters with paper-backed aluminium (PVC/Alu).

Cardboard box with 1 blister of 1, 3 or 6 chewable tablets or 3 blisters of 6 chewable tablets or 15 blisters of 1 chewable tablet.

Not all pack sizes may be marketed

Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Marketing Authorisation Holder (if different from distributor)

Boehringer Ingelheim Vetmedica GmbH

Marketing Authorisation Number

EU/2/13/159/001-020

Significant changes

Legal category

Legal category:POM-V

GTIN

GTIN description: NexGard Dog (S) x 3

GTIN:4028691568766

GTIN description: NexGard Dog (S) x 6

GTIN:4028691568797

GTIN description: NexGard Dog (M) x 3

GTIN:4028691568827

GTIN description: NexGard Dog (M) x 6

GTIN:4028691568858

GTIN description: NexGard Dog (L) x 3

GTIN:4028691568889

GTIN description: NexGard Dog (L) x 6

NOAH Compendium

GTIN:4028691568919

GTIN description: NexGard Dog (XL) x 3

GTIN:4028691568940

GTIN description: NexGard Dog (XL) x 6

GTIN:4028691568971