NexGard®

11 mg chewable tablets for dogs 2–4 kg
28 mg chewable tablets for dogs >4–10 kg
68 mg chewable tablets for dogs >10–25 kg
136 mg chewable tablets for dogs >25–50 kg

Manufactured by:
Boehringer Ingelheim Animal Health do Brasil Ltda,
Avenida Doutor Roberto Moreira, 5005,
Recanto dos Passaros, Paulinia, 13148-914 Sao Paulo, Brazil.

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France, 4 Chemin du Calquet, 31000 Toulouse, France.

Registration holder and repacker:
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STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each chewable tablet contains:

NexGard	Afoxolaner (mg)
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	68.0
chewable tablets for dogs >25–50 kg	136.0

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).

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.

PHARMACOKINETICS
After oral administration in dogs, afoxolaner was shown to have high systemic absorption following administration. The absolute bioavailability was 74%. The mean maximum concentration (Cmax) was 1,655 ± 332 ng/ml in plasma at 2-4 hours (Tmax) after a 2.5 mg/kg afoxolaner dose. Afoxolaner distributes into tissues with a volume of distribution of 2.6 ± 0.6 l/kg and a systemic clearance value of 5.0 ± 1.2 ml/hr/kg. The terminal plasma half-life is approximately 2 weeks in most dogs; however, half-life of afoxolaner can differ between dogs (e.g. in one study, t½ in Collies at 25 mg/kg bodyweight was up to 47.7 days) with no effect on safety. In vitro experiments demonstrated that P-glycoprotein efflux does not occur, confirming that afoxolaner is not a substrate for the P-glycoprotein transporters.
Afoxolaner in the dog is metabolized to more hydrophilic compounds and then eliminated. The metabolites and parent compound are eliminated from the body via urinary and biliary excretion with the majority eliminated in the bile. No evidence of enterohepatic recycling has been observed.

INDICATIONS
Treatment of flea infestation in dogs (*Ctenocephalides felis* and *C. canis)* for at least 5 weeks. 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).* One treatment kills ticks for up to one month.

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 case of hypersensitivity to the active substance or to any of the excipients.

ADVERSE REACTIONS:
Very rare (< 1 animal/ 10 000 animals treated, including isolated reports):
Digestive tract disorders[1] (vomiting[2], diarrhoea[2]),
Lethargy[2], anorexia[2],
Pruritus (itching)[2],
Neurological disorders (convulsion[2], ataxia (incoordination)[2], muscle tremor[2])

[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. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the product registration holder using the contact details in this leaflet.

TARGET SPECIES: Dogs

DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION: Oral use
Dosage: The veterinary medicinal product should be administered at a dose of 2.7 to 7mg/kg bodyweight of afoxolaner in accordance with the following table:

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

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.

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 case 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 mites 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.

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

INTERACTIONS WITH OTHER MEDICAMENTS: None known.

WITHDRAWAL PERIOD: Not applicable

SPECIAL STORAGE PRECAUTIONS: Please keep below 30°C. Keep in dry place. Keep out of the sight and reach of children.

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 may increase the resistance 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 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 to 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.

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.

Overdose (symptoms, emergency procedures, 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 PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY
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.

PACKING: Carton with 1 blister of 3 or 6 chewable tablets.

FOR VETERINARY USE ONLY.

Date of revision: January 2026
5LNEGAS3-006 13/XXX

Boehringer Ingelheim

LABEL CODE:	VERSION	COLORS
5LNEGAS3-006 **PRODUCT**: NEXGARD CHEWABLE TABLETS FOR DOGS **PACK SIZE**: 3 TABLETS and 6 TABLETS **COUNTRY**: MY **DIMENSIONS:** cm = 17 X 55	**VERSION**: **13** **MMM/YY**:	Black ! Please use the official PANTONE® (P) matching system for an accurate color representation.

Marketing approval:	**Regulatory** approval:	**GMP** approval:
COMPLETE NAME: **DATE:** **SIGNATURE:**	**COMPLETE NAME:** **DATE:** **SIGNATURE:**	**COMPLETE NAME:** **DATE:** **SIGNATURE:**