Afoxolaner Chewable Tablets 11.3mg/28.3mg/68mg/136mg

NexGard®

NAME OF THE VETERINARY MEDICINAL PRODUCT
NexGard 11.3 mg chewable tablets for dogs (2-4 kg)
NexGard 28.3 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)
afoxolaner

Manufactured by:
M/s. Boehringer Ingelheim Animal Health do Brasil Ltda., Fazenda São Francisco s/n, CEP 13140-970 Paulinia - São Paulo-Brazil

922828

Released by:
M/s Boehringer Ingelheim Animal Health France SCS, 4 Chemin du Calquet, 31000, Toulouse, France

Imported and Marketed in India by:
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STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)
Each 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
chewable tablets for dogs >25–50 kg	136

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

Dosage Form: Chewable tablets for oral administration

INDICATIONS
Treatment and prevention of flea infestation in dogs (Ctenocephalides felis and C. canis) for at least 1 month. 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, Dermacentor variabilis, Ixodes scapularis, Amblyomma americanum, Haemaphysalis longicornis, Ixodes rholocyclus).
One treatment prevents further ticks infestation for one month.

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

ADVERSE REACTIONS

Mild gastrointestinal effects (vomiting, diarrhoea), pruritus, lethargy, anorexia, and neurological signs (convulsions, ataxia and muscle tremors) have been reported very rarely. Most reported adverse reactions were self-limiting and of short duration.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)).
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).
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 inform your veterinary surgeon.

TARGET SPECIES: Dogs

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

Bodyweight of dog (kg)	Strength and number of chewable tablets to be administered			
	NexGard 11.3 mg	NexGard 28.3 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.
The tablets should not be divided.

Treatment schedule:
Treatment of flea *and tick infestations:*
Monthly intervals throughout the flea and/or tick seasons, based on local epidemiological situations.
Treatment of demodicosis (caused by Demodex canis):
Monthly administration of the product 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 product for two consecutive months. Further monthly administration of the product may be required based on clinical assessment and skin scrapings.

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

WITHDRAWAL PERIOD(S): Not applicable.

SPECIAL STORAGE PRECAUTIONS
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
This veterinary medicinal product does not require any special storage conditions and can be stored at room temperature.

SPECIAL WARNINGS
Special warnings for each target species:
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.
Special precautions for use in animals:
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.
Wash hands after handling the product.
Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects, or any adverse effect on the reproductive capacity of males and females. The safety of the veterinary medicinal product has not been established during pregnancy and lactation or in breeding dogs. Use only according to the benefit-risk assessment by the responsible veterinarian.
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 2-4 weeks.
"NOT FOR HUMAN USE; FOR ANIMAL TREATMENT ONLY"

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED: 10/2019
Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

OTHER INFORMATION
Afoxolaner is an insecticide and acaricide belonging to the isoxazoline family.
NexGard 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, and Haemaphysalis longicornis
NexGard kills fleas within 8 hours and ticks within 48h.
The product kills fleas before egg production and therefore prevents household contamination.
For each strength, the chewable tablets are available in the following pack sizes:
Carton with 1 blister of 1, 3 or 6 chewable tablets or 3 blisters of 6 chewable tablets or 15 blisters of 1 chewable tablet.

PRESCRIPTION DRUG- CAUTION
Not to be sold by retail without the prescription of a Registered Medical Practitioner.

Boehringer Ingelheim

PACK OPS LYON GRAPHIC ARTWORK APPROVAL

Code: 0 053 922828	VERSION PTG : 0142 Version : A 250716	COLORS
PRODUCT: NOT NEXGARD **COUNTRY:** INDE (IN) Dimensions à plat (mm): 170 x 550 Dimensions plié(e)s: 170 x 51 1201119	**INITIALS:** CS - Composer ET **VERSION - DATE:** A 28/11/19 11h45 B 10/12/19 15h00 C 12/12/19 16h30	Noir/Black Please use the official PANTONE® (P) matching system for an accurate color representation.
PRINTED BASIS CODE (if applicable): NA	**CANCEL AND REPLACE:** NA	

Marketing approval:	**Regulatory** approval:
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