NexGard®
(afoxolaner) Chewables

South Africa Reg. No. G4118 Act 36/1947
Namibia Reg. No. V16/18.3.6/1367 (NS2)
Zimbabwe Reg. No 2017/80.16.00/9764 (VMDG)

CHEWABLE TABLETS FOR DOGS

FOR ANIMAL USE ONLY.

NEXGARD® contains afoxolaner, an insecticide-acaricide for oral treatment and prevention of flea and tick infestations of dogs for one month following a single administration.

CAUTION.

INDICATIONS

- For the treatment and prevention of flea infestation in dogs *(Ctenocephalides felis and C. canis)* for at least 1 month.
- Starts killing existing fleas 30 minutes after administration; 100% efficacy achieved by 8 hours.
- Elimination of new adult fleas on the dog within 12 hours; kills fleas before egg production and therefore prevents the risk of household contamination.
- Can be used as part of a treatment strategy for the control of Flea Allergy Dermatitis (FAD).
- For the treatment and prevention of tick infestation in dogs *(Rhipicephalus sanguineus, Haemaphysalis spp.)* plus various other spp.
- **For optimal flea and tick control monthly administrations are recommended.**

CONTRA INDICATIONS

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

COMPOSITION

Afoxolaner 2,27 % w/w.

DOSAGE AND DIRECTIONS FOR USE

- Use only as directed.
- Administer orally at monthly intervals to provide the recommended dosage of 2, 5 mg/kg of afoxolaner per kg bodyweight.
- The following dosing table serves as a guide:

PRESENTATION	CHEW SIZE (G)	AFOXOLANER (MG/CHEW)
Very small dogs (2–4 kg)	0,5	11,3
Small dogs (4,1-10 kg)	1,25	28,3
Medium dogs (10,1–25 kg)	3	68,0
Large dogs (25,1–50 kg)	6	136,0

- For dogs above 50 kg, administer the appropriate combination of chewable tablets.
- NEXGARD® is recommended for use in dogs and puppies 8 weeks of age and older.

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WARNINGS

- Keep out of reach of children, uninformed persons and animals.
- After treatment with NEXGARD®, most ticks will generally be killed within 48 hours after infestation. However the attachment of single ticks cannot be excluded and so transmission of infectious diseases cannot be completely excluded if conditions are unfavourable.
- NEXGARD® may cause vomiting and diarrhoea in some dogs.
- Use during pregnancy, lactation or breeding:

  No data have been generated in dogs used for breeding. However, in laboratory species (rats and rabbits), afoxolaner has not produced any evidence of teratogenic effects, nor any adverse effect on the reproductive capacity in males and females.

  Safety in pregnant and lactating animals has not been determined.
- Although this remedy has been extensively tested under a large variety of conditions, failure thereof may ensure as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

PRECAUTIONS

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.
- Remove only one chewable tablet at a time from the foil-backed blister card.
- Administer the chewable tablet in a manner that encourages the dog to chew rather than to swallow without chewing.
- Care should be taken to ensure that the dog consumes the complete dose; treated animals should be observed for a few minutes after administration to ensure that part of the dose is not lost or rejected.

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

- In case of accidental ingestion, seek medical advice immediately and show the package insert or the label to the physician.

METHOD OF ADMINISTRATION

- Administer the chewable tablets appropriate for your dog's weight at monthly intervals. Because dogs find NEXGARD® palatable, the product can be offered to the dog by hand. Alternatively, chewable tablets can be added to a small amount of dog food, or dosed manually.

KNOWN CLINICAL SIGNS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

- Treatment is symptomatic and supportive.
- Afoxolaner was well tolerated when administered to 8-week old Beagle dogs at 1, 3, or 5X the maximum potential exposure dose of 6.3 mg/kg at three 28-day dose intervals followed by three 2-week dose intervals for a total of 6 doses.

PRESENTATIONS

The veterinary medicinal product is individually packaged in thermoformed blisters.

STORAGE

Store in a dry place, at or below 30°C.

REGISTRATION HOLDER

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