PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NexGard 11 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Afoxolaner 11.3 mg

2–4 kg

3. PACKAGE SIZE

1 chewable tablet
3 chewable tablets
6 chewable tablets
15 chewable tablets
18 chewable tablets (3 blister of 6 tablets)

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 04491/5027

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NexGard

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

2–4 kg

Afoxolaner

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

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

2. Composition

Each chewable tablet contains:

Active substance:

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 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).

3. Target species

Dogs.

4. Indications for use

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. 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.

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*).

5. Contraindications

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

6. 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 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-infection with fleas, ticks or mites should be considered, and these should be treated as necessary with an appropriate product.

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.

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.

Overdose:
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.

7. Adverse events

Dogs:

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 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 marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

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**			
	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.

The tablets are chewable and palatable to most dogs. If the dog does not accept the tablets directly they may be administered with food. Chewable tablets may be administered by the animal owner at home.

9. Advice on correct administration

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 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.

10. Withdrawal periods

Not applicable.

11. 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 packaging after Exp. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 04491/5027 (11 mg)
Vm 04491/5028 (136 mg)
Vm 04491/5029 (28 mg)
Vm 04491/5030 (68 mg)

For each strength, the chewable tablets are available in the following pack sizes:
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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim am Rhein
Germany

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

Local representatives and contact details to report suspected adverse reactions:

United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Limited
Bracknell, RG12 8YS, UK
Tel: + 44 1344 746957

17. Other information

Afoxolaner is an insecticide and acaricide belonging to the isoxazoline family.

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

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

For animal treatment only.

POM-V

Gavin Hall
Approved: 12 December 2024