ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

afoxolaner

2. STATEMENT OF ACTIVE SUBSTANCES

Afoxolaner 136 mg

3. PHARMACEUTICAL FORM

Chewable tablets

4. PACKAGE SIZE

1 chewable tablet
3 chewable tablets
6 chewable tablets
15 chewable tablets
18 chewable tablets

5. TARGET SPECIES

Dogs >25–50 kg

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use. Oral use

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE,

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH 55216 Ingelheim/Rhein
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/5028

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NexGard 136 mg dogs >25-50 kg

afoxolaner

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

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

2. 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)
afoxolaner

3. 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
chewable tablets for dogs >25–50 kg	136

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

4. 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*).

5. CONTRAINDICATIONS

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

6. 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.

7. TARGET SPECIES

Dogs

8. 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 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.
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.

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.

9. 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.

10. WITHDRAWAL PERIOD(S)

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 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.

12. 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:
Can be used in breeding, pregnant and lactating dogs.
The safety of the veterinary medicinal product has not been established in breeding males.
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects, or any adverse effect on the reproductive capacity of males. In breeding males, 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.

13. 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

01/2023

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

15. 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, 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 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.

Not all pack sizes may be marketed.

Approved 17 April 2023