PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEXGARD SPECTRA 9 mg / 2 mg chewable tablets for dogs 1.35–3.5 kg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each chewable tablet contains: 9.375 mg afoxolaner and 1.875 mg milbemycin oxime

3. PACKAGE SIZE

1 chewable tablet
3 chewable tablets
6 chewable tablets (1 blister of 6 tablets)
6 chewable tablets (2 blisters of 3 tablets)
15 chewable tablets

4. TARGET SPECIES

Dogs.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the blister in the outer carton in order to protect from light.

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 04491/5035

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V ('To be supplied only on veterinary prescription')

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEXGARD SPECTRA

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1.35–3.5 kg

9 mg / 2 mg afoxolaner / milbemycin oxime

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEXGARD SPECTRA 9 mg / 2 mg chewable tablets for dogs 1.35–3.5 kg
NEXGARD SPECTRA 19 mg / 4 mg chewable tablets for dogs >3.5–7.5 kg
NEXGARD SPECTRA 38 mg / 8 mg chewable tablets for dogs >7.5–15 kg
NEXGARD SPECTRA 75 mg / 15 mg chewable tablets for dogs >15–30 kg
NEXGARD SPECTRA 150 mg / 30 mg chewable tablets for dogs >30–60 kg

2. COMPOSITION

Each chewable tablet contains:

Active substances:

NEXGARD SPECTRA	Afoxolaner (mg)	Milbemycin oxime (mg)
chewable tablets for dogs 1.35 – 3.5 kg	9.375	1.875
chewable tablets for dogs >3.5– 7.5 kg	18.75	3.75
chewable tablets for dogs >7.5– 15 kg	37.50	7.50
chewable tablets for dogs >15– 30 kg	75.00	15.00
chewable tablets for dogs >30– 60 kg	150.00	30.00

Mottled red to reddish brown, circular shaped chewable tablets (for dogs 1.35 – 3.5 kg) or rectangular shaped chewable tablets (for dogs >3.5 – 7.5 kg, for dogs >7.5 – 15 kg, for dogs >15 – 30 kg and for dogs >30 – 60 kg).

3. TARGET SPECIES

Dogs.

4. INDICATIONS FOR USE

For dogs with, or at risk from, mixed infestations by external and internal parasites. The veterinary medicinal product is only indicated for use when use against ticks, fleas or mites and one or more of the other target parasites is indicated at the same time.

External parasites:
Treatment of flea (*Ctenocephalides felis* and *C. canis*) and tick (*Dermacentor reticulatus, Ixodes ricinus, Ixodes hexagonus, Rhipicephalus sanguineus, Hyalomma marginatum*) infestations in dogs.
Fleas and ticks must attach to the host and commence feeding in order to be exposed to the active substance.

The veterinary medicinal product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

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*).

Gastrointestinal nematodes
Treatment of adult gastrointestinal nematodes of the following species: roundworms (*Toxocara canis* and *Toxascaris leonina*), hookworms (*Ancylostoma caninum, Ancylostoma braziliense and Ancylostoma ceylanicum*) and whipworm (*Trichuris vulpis*).

Other nematodes
Prevention of heartworm disease (*Dirofilaria immitis* larvae) with monthly administration.
Prevention of angiostrongylosis (by reduction of the level of infection with immature adult (L5) and adult stages of *Angiostrongylus vasorum*) with monthly administration.
Prevention of establishment of thelaziosis (adult *Thelazia callipaeda* eyeworm infection) with monthly administration.

5. CONTRAINDICATIONS

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

6. SPECIAL WARNINGS

Special warnings:
Fleas and ticks need to start feeding on the host to become exposed to the substance afoxolaner; therefore, the risk of the transmission of diseases by fleas and ticks cannot be excluded.

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC 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.

In the absence of risk of co-infestation by external and internal parasites, a narrow spectrum product should be used.

The possibility that other animals in the same household can be a source of re-infestation with fleas, ticks, mites or gastrointestinal nematodes should be considered, and these should be treated as necessary with an appropriate product.

Ancylostoma ceylanicum is reported as being endemic only in Southeast Asia, China, India, Japan, some Pacific islands, Australia, the Arab Peninsula, South Africa and South America.

Heartworm disease prevention is critical. To minimise the risk of resistance selection, it is recommended that dogs should be checked for both circulating antigens and blood microfilariae at the beginning of each season of preventative treatment. Only negative animals should be treated.

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 dogs less than 1.35 kg bodyweight should be based on a benefit-risk assessment by the responsible veterinarian.

In regions where heartworm disease is present, dogs should be tested for existing heartworm infestation prior to administration of the veterinary medicinal product. At the discretion of the veterinarian, infested dogs should be treated with an adulticide to remove adult heartworms. The veterinary medicinal product is not indicated for removal of microfilariae from positive dogs.

The recommended dose should be strictly observed in collies or related breeds.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
- This product may cause gastrointestinal disturbances if ingested.
- Keep tablets in the blister packs until required and keep the blisters in the outer carton.
- In case of accidental ingestion, particularly in the case of children, seek medical advice immediately and show the package leaflet or the label to the physician.
- Wash hands after use.

Pregnancy and lactation:
Can be used in pregnant and lactating dogs.

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 birth defects, or any adverse effect on the reproductive capacity in males.

Interaction with other medicinal products and other forms of interaction:
Milbemycin oxime is a substrate for P-glycoprotein (P-gp) and therefore could interact with other P-gp substrates (for example, digoxin, doxorubicin) or other macrocyclic lactones. Therefore, concomitant treatment with other P-gp substrates could lead to enhanced toxicity.

Overdose:
No adverse reactions were observed in eight-week old healthy puppies after 6 treatments at up to 5 times the maximum dose.

7. ADVERSE EVENTS

Dogs:

Uncommon (1 to 10 animals / 1 000 animals treated):
Vomiting[1], diarrhoea[1]
Lethargy[1], anorexia[1],
Pruritus (itching)[1]

Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Erythema (redness)
Neurological signs (convulsion, ataxia (incoordination) and muscle tremor).

[1] Generally 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 2.50 to 6.94 mg/kg of afoxolaner and 0.50 to 1.39 mg/kg of milbemycin oxime in accordance with the following table:

Bodyweight (kg) of dog	**Number and strength of chewable tablet to be administered**				
	NEXGARD SPECTRA 9 mg / 2 mg	NEXGARD SPECTRA 19 mg / 4 mg	NEXGARD SPECTRA 38 mg / 8 mg	NEXGARD SPECTRA 75 mg / 15 mg	NEXGARD SPECTRA 150 mg / 30 mg
1.35–3.5	1				
>3.5–7.5		1			
>7.5–15			1		
>15–30				1	
>30–60					1

For dogs above 60 kg appropriate combinations of chewable tablets should be used.
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.

9. ADVICE ON CORRECT ADMINISTRATION

Treatment schedule:
The need for and frequency of re-treatment(s) should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

Treatment of flea and tick infestations and gastrointestinal worms:
The veterinary medicinal product can be used as part of the seasonal treatment of fleas and ticks (replacing a product authorised for the treatment of fleas/ticks only) in dogs with diagnosed concurrent gastrointestinal worm infestations. A single treatment is effective for gastrointestinal worms.
Efficacy of the treatment against flea and tick infestations lasts for one month. Further treatments may be indicated throughout the flea and/or tick season. Ask your veterinarian how to continue flea and tick treatment.

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 administrations 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 may be recommended as some animals may require a second treatment.

Prevention of heartworm disease:
The veterinary medicinal product kills Dirofilaria immitis larvae (heartworm) up to one month after their transmission by mosquitoes. Therefore, the veterinary medicinal product should be administered at regular monthly intervals during the time of the year when mosquitoes are present, starting in the month after the first expected exposure to them.

Treatment should continue until 1 month after the last exposure to mosquitoes. To establish a treatment routine, it is recommended that the same day or date be used each month. When replacing another heartworm preventative product in a heartworm prevention programme, the first treatment with the veterinary medicinal product should start on the date when the former medication was due to have been administered.

Dogs living in heartworm endemic areas (where heartworm disease is present), or those which have travelled to endemic areas, may be infested with adult heartworms. No therapeutic effect against adult Dirofilaria immitis has been established. It is therefore recommended that all dogs 8 months of age or more, living in heartworm endemic areas, should be tested for existing adult heartworm infestation before being treated with the veterinary medicinal product for heartworm prevention.

Prevention of Angiostrongylosis:
In endemic areas, monthly administration of the veterinary medicinal product will reduce the level of infection with immature adults (L5) and adults of *Angiostrongylus vasorum* in the heart and lungs.

Prevention of thelaziosis:
Monthly administration of the veterinary medicinal product prevents establishment of infection with adult *Thelazia callipaeda* eyeworm.

10. WITHDRAWAL PERIODS

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the blister in the outer carton in order to protect from light.
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.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 04491/5035

For each strength, the chewable tablets are available in the following pack sizes:
Cardboard box with 1 blister containing 1, 3 or 6 chewable tablets or 15 blisters containing 1 chewable tablet or 2 blisters containing 3 chewable tablets.
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

October 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
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Local representatives and contact details to report suspected adverse reactions:

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17. OTHER INFORMATION

Afoxolaner is an insecticide and acaricide belonging to the isoxazoline family. It is active against adult fleas as well as against several tick species such as *Rhipicephalus sanguineus*, *Dermacentor reticulatus* and *D. variabilis*, *Ixodes ricinus, Ixodes hexagonus* and *I. scapularis*, *Amblyomma americanum, Haemaphysalis longicornis*, and *Hyalomma marginatum*.

Afoxolaner kills fleas before egg production and therefore prevents the risk of household contamination.

Milbemycin oxime is an antiparasitic endectocide belonging to the group of macrocyclic lactones.

It is active against several gastrointestinal worms (*Toxocara canis, Toxascaris leonina, Ancylostoma caninum, Ancylostoma braziliense, Ancylostoma ceylanicum, Trichuris vulpis*), the adults and immature adults (L5) of lungworm *Angiostrongylus vasorum* and larvae of the heartworm *Dirofilaria immitis*.

Approved 02 April 2024