SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEXGARD SPECTRA 38 mg / 8 mg chewable tablets for dogs >7.5–15 kg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substances:

NEXGARD SPECTRA	Afoxolaner (mg)	Milbemycin oxime (mg)
chewable tablets for dogs >7.5–15 kg	37.50	7.50

Excipients:

Qualitative composition of excipients and other constituents
Maize starch
Soy protein fines
Beef braised flavouring
Povidone (E1201)
Macrogol 400
Macrogol 4000
Macrogol 15 hydroxystearate
Glycerol (E422)
Triglycerides, medium-chain
Citric acid monohydrate (E330)
Butylhydroxytoluene (E321)

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. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

For dogs with, or at risk from, mixed infestations by external and internal parasites. The veterinary medicinal product is only indicated 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 infestations (*Ctenocephalides felis* and *C. canis*). The veterinary medicinal product provides immediate and persistent killing activity for 5 weeks. The product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).

Treatment of tick infestations (*Dermacentor reticulatus, Ixodes ricinus, Ixodes hexagonus, Rhipicephalus sanguineus, Hyalomma marginatum*). The veterinary medicinal product provides immediate and persistent killing activity for 4 weeks.

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*).

Gastrointestinal nematodes
Treatment of infestations with 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.

For reduction of the risk of infection with *Babesia canis* via transmission by *Dermacentor reticulatus* for 28 days. The effect is indirect due to the activity of the veterinary medicinal product against the vector.

For reduction of the risk of infection with *Dipylidium caninum* via transmission by *Ctenocephalides felis* for 30 days. The effect is indirect due to the activity of the veterinary medicinal product against the vector.

3.3 Contraindications

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

3.4 Special warnings

Fleas and ticks need to start feeding on the host to become exposed to afoxolaner; therefore, the risk of the transmission of vector-borne diseases 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 South-East Asia, China, India, Japan, some Pacific islands, Australia, the Arab Peninsula, South Africa and South America.

Maintenance of the efficacy of macrocyclic lactones is critical for *Dirofilaria immitis* control. 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.

3.5 Special precautions for use

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 heartworm endemic areas, 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 microfilariae clearance.

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.

Special precautions for the protection of the environment
Not applicable.

3.6 Adverse events

Dogs:

Uncommon (1 to 10 animals / 1 000 animals treated):	Vomiting[1], diarrhoea[1], Lethargy[1], anorexia[1], Pruritus[1].
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Erythema Neurological signs (convulsion, ataxia and muscle tremor).

[1]Generally self-limiting and of short duration.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product.
Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 teratogenic effects, or any adverse effect on the reproductive capacity in males.

3.8 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.

3.9 Administration routes and dosage

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 of dog (kg)	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.

Method of administration:
The tablets are chewable and palatable to most dogs. If the dog does not accept the tablets directly they may be administered with food.

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 nematodes:
The veterinary medicinal product can be used as part of the seasonal treatment of fleas and ticks (replacing treatment with a monovalent flea and tick product) in dogs with diagnosed concurrent gastrointestinal nematode infestations. A single treatment is effective for the treatment of gastrointestinal nematodes.

Treatment of demodicosis (caused by Demodex canis):
Administration of the veterinary medicinal product leads to a marked improvement of clinical signs. Treatment should be continued 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 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 vectors are present, starting in the month after the first expected exposure to mosquitoes.
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, 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP54AB51.

4.2 Pharmacodynamics

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

Afoxolaner acts as an antagonist at ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA). Isoxazolines, among the chloride channel modulators, bind to a distinct and unique target site within the insect GABACls, thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. Prolonged afoxolaner-induced hyperexcitation results in uncontrolled activity of the central nervous system and death of insects and acarines. The selective toxicity of afoxolaner between insects, acarines and mammals may be inferred by the differential sensitivity of the insects and acarines' GABA receptors versus mammalian GABA receptors.

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:
Milbemycin oxime is an antiparasitic endectocide belonging to the group of macrocyclic lactones. Milbemycin oxime contains two major components, A3 and A4 (ratio of 20:80 for A3:A4). It is a fermentation product of *Streptomyces milbemycinicus*. Milbemycin oxime acts by disrupting the glutamate neuro-transmission in invertebrates. Milbemycin oxime increases glutamate binding with consequent enhanced chloride ion flow into the cell. This leads to hyperpolarisation of the neuromuscular membrane resulting in paralysis and death of the parasites.

Milbemycin oxime 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 heartworm (*Dirofilaria immitis* larvae).

4.3 Pharmacokinetics

The systemic absorption of afoxolaner is high. The absolute bioavailability is 88%. The mean maximum concentration (C_{max}) is 1822 ± 165 ng/ml in plasma found 2–4 hours (T_{max}) after a 2.5 mg/kg afoxolaner dose.

Afoxolaner distributes into tissues with a volume of distribution of 2.6 ± 0.6 l/kg and a systemic clearance value of 5.0 ± 1.2 ml/h/kg. The terminal plasma half-life is approximately 2 weeks in dogs.

Milbemycin oxime plasma concentrations peak quickly within the first 1–2 hours (T_{max}) indicating that absorption from the chewable tablets is fast. The absolute bioavailability is 81% and 65% for the A3 and A4 forms, respectively. The terminal half-lives and maximum concentrations (C_{max}) following oral administration are 1.6 ± 0.4 days and 42 ± 11 ng/ml for the A3 form, 3.3 ± 1.4 days and 246 ±71 ng/ml for the A4 form.

Milbemycin oxime distributes into tissues with a volume of distribution of 2.7 ± 0.4 l/kg and 2.6 ± 0.6 l/kg for the A3 and A4 forms, respectively. Both forms have low systemic clearance (75 ± 22 ml/h/kg for the A3 form and 41 ± 12 ml/h/kg for the A4 form).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is individually packaged in thermoformed laminated PVC blisters with paper-backed aluminium (PVC/Alu).

Cardboard box with one blister of 1, 3 or 6 chewable tablets or 15 blisters of 1 chewable tablet or 2 blisters of 3 chewable tablets.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 61700/5034

8. DATE OF FIRST AUTHORISATION

14 January 2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 11 February 2026