ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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. QUALITATIVE AND QUANTITATIVE 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

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

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. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

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*).

3.3 Contraindications

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

3.4 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 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.

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

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/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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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[2]

	Neurological disorders (convulsion[2], ataxia[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 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.
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.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

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.

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:
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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 to 4 weeks.

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: QP53BE01.

4.2 Pharmacodynamics

Afoxolaner is an insecticide and acaricide belonging to the isoxazoline family. Afoxolaner acts at ligand-gated chloride channels, in particular those gated by the neurotransmitter gamma-aminobutyric acid (GABA), thereby blocking pre- and post-synaptic transfer of chloride ions across cell membranes. This results in uncontrolled activity of the central nervous system and death of insects or acarines. The selective toxicity of afoxolaner between insect/acarines and mammals may be inferred by the differential sensitivity of the insect/acarines' GABA receptors versus mammalian receptors.

Afoxolaner 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*.

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

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

4.3 Pharmacokinetics

After oral administration in dogs, afoxolaner was shown to have high systemic absorption following administration. The absolute bioavailability was 74 %. The mean maximum concentration (C_{max}) was 1,655 ± 332 ng/ml in plasma at 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/hr/kg. The terminal plasma half-life is approximately 2 weeks in most dogs; however, half-life of afoxolaner can differ between dogs (e.g. in one study, $t_{½}$ in Collies at 25 mg/kg bodyweight was up to 47.7 days) with no effect on safety. *In vitro* experiments demonstrated that P-glycoprotein efflux does not occur, confirming that afoxolaner is not a substrate for the P-glycoprotein transporters.

Afoxolaner in the dog is metabolised to more hydrophilic compounds and then eliminated. The metabolites and parent compound are eliminated from the body via urinary and biliary excretion with the majority eliminated in the bile. No evidence of enterohepatic recycling has been observed.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

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

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 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.

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

Medicines should not be disposed of via wastewater or household waste.

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(S)

EU/2/13/159/001–020

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 11/02/2014

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NexGard 11 mg chewable tablets
NexGard 28 mg chewable tablets
NexGard 68 mg chewable tablets
NexGard 136 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Afoxolaner 11.3 mg
Afoxolaner 28.3 mg
Afoxolaner 68 mg
Afoxolaner 136 mg

2–4 kg
> 4–10 kg
> 10–25 kg
> 25–50 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

EU/2/13/159/001 – 11.3 mg, 1 chewable tablet
EU/2/13/159/002 – 11.3 mg, 3 chewable tablets
EU/2/13/159/003 – 11.3 mg, 6 chewable tablets
EU/2/13/159/004 – 28.3 mg, 1 chewable tablet
EU/2/13/159/005 – 28.3 mg, 3 chewable tablets
EU/2/13/159/006 – 28.3 mg, 6 chewable tablets
EU/2/13/159/007 – 68.0 mg, 1 chewable tablet
EU/2/13/159/008 – 68.0 mg, 3 chewable tablets
EU/2/13/159/009 – 68.0 mg, 6 chewable tablets
EU/2/13/159/010 – 136.0 mg, 1 chewable tablet
EU/2/13/159/011 – 136.0 mg, 3 chewable tablets
EU/2/13/159/012 – 136.0 mg, 6 chewable tablets
EU/2/13/159/013 – 11.3 mg, 15 chewable tablets
EU/2/13/159/014 – 28.3 mg, 15 chewable tablets
EU/2/13/159/015 – 68.0 mg, 15 chewable tablets
EU/2/13/159/016 – 136.0 mg, 15 chewable tablets
EU/2/13/159/017 – 11.3 mg, 18 chewable tablets
EU/2/13/159/018 – 28.3 mg, 18 chewable tablets
EU/2/13/159/019 – 68.0 mg, 18 chewable tablets
EU/2/13/159/020 – 136.0 mg, 18 chewable tablets

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NexGard

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

2–4 kg
> 4–10 kg
> 10–25 kg
> 25–50 kg

Afoxolaner

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

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 or household waste.

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

EU/2/13/159/001–020

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. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

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

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Boehringer Ingelheim Animal
Health Belgium SA
Avenue Arnaud Fraiteurlaan 15-23,
1050 Bruxelles/Brussel/Brüssel
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United Kingdom (Northern Ireland)
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Tel: +353 1 291 3985

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.