PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
PATIENT PACKAGE INSERT FOR A VETERINARY MEDICINE
The medicine is dispensed with a veterinarian's prescription only
For animal use only

1) NAME OF THE VETERINARY MEDICINE, ITS FORM AND STRENGTH:

NEXGARD 11 mg VETERINARY
NEXGARD 28 mg VETERINARY
NEXGARD 68 mg VETERINARY
NEXGARD 136 mg VETERINARY

Chewable tablets for dogs

2) THE ACTIVE INGREDIENT AND ITS CONCENTRATION PER DOSAGE UNIT:

Name of the medicine	Amount of active ingredient in each chewable tablet
Nexgard 11 mg Veterinary	Afoxolaner 11.3 mg
Nexgard 28 mg Veterinary	Afoxolaner 28.3 mg
Nexgard 68 mg Veterinary	Afoxolaner 68 mg
Nexgard 136 mg Veterinary	Afoxolaner 136 mg

For the list of inactive and allergenic ingredients in the medicine – see section 13.

Read this leaflet carefully in its entirety before using the medicine.
This leaflet contains concise information about the medicine. If you have further questions, refer to a veterinarian or to a pharmacist.

3) WHAT IS THE MEDICINE INTENDED FOR?
The medicine is intended for dogs, to treat flea (*Ctenocephalides felis and C. canis*) infestations for at least 5 weeks. The medicine can be used as part of a treatment, including for skin inflammation caused by flea allergy dermatitis (FAD).
The medicine is intended for dogs to treat tick (*Dermacentor reticulatus, Ixodes ricinus and Rhipicephalus sanguineus*) infestations. A single treatment is effective for up to one month.
The fleas and ticks must be on the dog's fur and initiate active feeding in order to be exposed to the active ingredient of the medicine.
The medicine treats demodicosis skin infestations (caused by *Demodex canis*), which causes loss of hair from the dog's fur and sores on the skin.
The medicine treats sarcoptic mange skin infestations (caused by the *Sarcoptes scabiei var. canis* tick), which causes scabies in the dog's fur.

Therapeutic group: The medicine belongs to the systemic anti-ectoparasitics group.

4) CONTRAINDICATIONS:

Do not use the medicine:
- If the dog is sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine.
  The active ingredient is listed in section 2 and the additional ingredients are listed in section 13.

5) SIDE EFFECTS:
As with any medicine, use of this medicine may cause side effects in some dogs. Do not be alarmed by the list of side effects. The dog may not suffer from any of them.
Very rare side effects (frequency of less than one case in every 10,000 dogs): mild effects on the digestive system (vomiting, diarrhea), pruritus, lethargy or anorexia (eating disturbance), neurological signs (convulsions, ataxia, and muscle tremor). These side effects generally pass on their own within a short time.
If one of the side effect worsens, or if the dog suffers from a side effect not mentioned in the leaflet, consult with the veterinarian.
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

6) TARGET ANIMALS:
The medicine is intended for use in dogs only.

7) ADMINISTRATION FORM AND DOSAGE FOR ANIMALS:
Always use in accordance with the veterinarian's instructions. Check with the veterinarian or pharmacist if you are uncertain. The dosage and treatment regimen will be determined by the veterinarian only.
Do not exceed the recommended dosage.

Administration form: Chewable tablets.
Dosage: The dose is calculated by 2.7-6.9 mg afoxolaner per kg dog body weight.
Nexgard 11 mg Veterinary: one tablet is appropriate for dogs weighing 2-4 kg.
Nexgard 28 mg Veterinary: one tablet is appropriate for dogs weighing over 4 kg and up to 10 kg.
Nexgard 68 mg Veterinary: one tablet is appropriate for dogs weighing over 10 kg and up to 25 kg.
Nexgard 136 mg Veterinary: one tablet is appropriate for dogs weighing over 25 kg and up to 50 kg.
The dosage for dogs weighing over 50 kg will be provided by combining several chewable tablets of suitable strengths. Do not halve the chewable tablets.

Administration frequency:
- Treatment of flea and tick infestations: The treatment should be repeated **once a month** throughout the flea and tick season, based on evaluation of likelihood of flea and tick infestations.
- Treatment of demodicosis skin infestations (caused by *Demodex canis*): The treatment should be repeated **once a month** until two skin tests of two consecutive months show that the disease has passed. In cases of severe infection, prolonged treatment may be necessary. There may be a need to treat the dog for additional diseases.
- Treatment of sarcoptic mange skin infestations (caused by the *Sarcoptes scabiei var. canis* tick): The treatment should be repeated **once a month** for two consecutive months. Further administration of the medicine may be needed based on the dog's pruritus and the veterinarian's assessment of the condition.

Do not give medicines in the dark! Check the label and dose each time you give the medicine to the dog. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the veterinarian or pharmacist.

8) HOW THE MEDICINE IS USED:
- The tablets are chewable and palatable to most dogs.
- If the dog is not willing to chew the tablets, they can be given with food.
- Do not halve the chewable tablets.

9) WITHDRAWAL PERIOD:
Withdrawal time before slaughter: Not relevant. The medicine is intended for dogs only.

10) WARNINGS:
- **Special warnings regarding use in the target animal:** The medicine works when the fleas and ticks are in and actively feeding on the dog's fur. Therefore, as long as the fleas and ticks have not actively eaten, the dog who just received the medicine may still spread the fleas and ticks to other dogs.
- **Special warnings regarding safety of use of the medicine in animals:** In the absence of adequate data to date, treatment of puppies younger than 8 weeks of age and/or dogs weighing less than 2 kg should be after the attending veterinarian weighs the risk versus benefit of use of this medicine in such cases.
- **Special warnings regarding the safety of the person handling the medicine:** To prevent children from gaining access to the medicine, remove only one chewable tablet at a time from the package. After taking out the tablet, return the tray ("blister") with the remaining tablets to the carton box. Wash hands after using the medicine.
  If someone accidentally swallowed the medicine, particularly if it was a child, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
- **Additional warnings:** If the dog has received an overdose, immediately refer to a veterinarian and bring the package of the medicine with you.
- **Pregnancy and lactation:** The safety of use of the medicine in pregnant and lactating dogs has not been established. In such cases, the attending veterinarian must weigh the risk versus benefit of use of this medicine.
  Laboratory studies performed in rabbits and rats did not indicate a teratogenic effect or an effect on male and female reproductive ability.
- **Interactions with other medicines, and other forms of interactions:**
  None known.
  If the dog is receiving, or if the dog has recently received, other medicines and other preparations (including preparations for treatment of ectoparasites or endoparasites), inform the veterinarian or pharmacist.
- **Overdosage:** No side effects were observed in Beagle puppies over 8 weeks of age when treated 6 times with a dosage 5 times the maximum dosage, at intervals of 2-4 weeks.
- **Incompatibility:** None known.

11) STORAGE INSTRUCTIONS:
- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store at a temperature below 30°C.

12) INSTRUCTIONS FOR THE DISPOSAL OF THE MEDICINE/ MEDICINE RESIDUES AFTER USE:
- Do not discard medicines in the toilet or with the household waste.
- Ask your pharmacist or veterinarian how to dispose of medicines that have expired or that are no longer required. These measures will help protect the environment.

13) FURTHER INFORMATION:
- **In addition to the active ingredient, the medicine also contains the following inactive ingredients:**
  Maize Starch, Soy Protein Fines q.s., Beef Braised Type Flavor, Povidone K30, Macrogol 400, Macrogol 4000, Macrogol 15 Hydroxystearate, Glycerol, Triglycerides Medium-Chain (MCT).
- **What the medicine looks like and the contents of the package:**
  Nexgard 11 mg Veterinary: The medicine looks like a round, red to reddish-brown tablet.
  Nexgard 28 mg Veterinary: The medicine looks like a rectangular, red to reddish-brown tablet.
  Nexgard 68 mg Veterinary: The medicine looks like a rectangular, red to reddish-brown tablet.
  Nexgard 136 mg Veterinary: The medicine looks like a rectangular, red to reddish-brown tablet.
- The tablets are packaged in plastic trays ("blisters"), which are packaged in carton boxes.
- **Package size:** The medicine is supplied in carton boxes containing one plastic tray with 1, 3 or 6 chewable tablets or three plastic trays with 6 chewable tablets or fifteen plastic trays with 1 chewable tablet.
- The number of plastic trays in each carton box may differ between pack sizes.
- The number of tablets in the package is indicated on the carton box.
- Not all pack sizes may be marketed.
- **Registration holder:** Beit-Erez Havat Milatin Ltd., P.O.B. 209, Mishmar Hashiv'a 5029700.
- **Manufacturer:** Boehringer Ingelheim Vetmedica GmbH, Ingelheim Am Rein, Germany.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Nexgard 11 mg Veterinary: 158-33-34664-00
Nexgard 28 mg Veterinary: 158-34-34665-00
Nexgard 68 mg Veterinary: 158-35-34666-00
Nexgard 136 mg Veterinary: 158-36-34667-00

The medicines are intended for male and female dogs only.
Revised in: 03/2023 according to the Ministry of Health guidelines.