

**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:

### BROADLINE VETERINARY

Drops (solution)

#### 2. THE ACTIVE INGREDIENTS AND THEIR CONCENTRATION PER DOSAGE UNIT:

	Fipronil	(S)-Methoprene	Praziquantel	Eprinomectin
In a 0.3 ml dose	24.9 mg	30 mg	24.9 mg	1.2 mg
In a 0.9 ml dose	74.7 mg	90 mg	74.7 mg	3.6 mg

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

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

#### 3. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for cats, for treatment and prevention of infestations by tapeworms (cestodes), roundworms (nematodes) and various external parasites (ectoparasites). The medicine is used when there is a mixed infestation with all three types of these parasites in the cat.

Consult a veterinarian to confirm that the medicine is suitable for treatment of the types of parasites the cat has.

The medicine treats the following strains of tapeworms (cestodes):

- *Dipylidium caninum*, *Taenia taeniaeformis*, *Echinococcus multilocularis*, *Joyeuxiella pasqualei* (adult) and *Joyeuxiella luhmanni* (adult).

The medicine treats the following strains of roundworms (nematodes):

- Treats gastrointestinal roundworm strains: *Toxocara cati* L3 and L4 larvae and adults, *Ancylostoma tubaeforme* L4 larvae and adults, adult forms of *Toxascaris leonina* and *Ancylostoma braziliense*.
- Treats infestations by vesical worms (*Capillaria plica*).
- Prevents infestation by heartworm larvae (heartworm disease ; *Dirofilaria immitis*) for one month.
- Treats lungworm larvae infestations (*Aelurostrongylus abstrusus* L3 and L4 larvae and adults, and *Troglostrongylus brevior* L4 larvae and adults).

The medicine treats the following strains of external parasites (ectoparasites):

- Treats and prevents infestations by fleas (*Ctenocephalides felis*). Eliminates the fleas within 24 hours. One treatment prevents development of fleas in the area and reinfestation, for one full month.
- The medicine may be used in the cat as part of a combination treatment for flea allergy caused by fleas.
- Treats and prevents infestations by ticks (*Ixodes ricinus*). Eliminates the ticks within 48 hours. One treatment prevents infestation for 3 weeks.
- Prevents environmental flea contamination by inhibiting development stages (eggs, larvae, pupae) for one month.
- Treats and prevents infestation by notoedric mange mites (*Notoedres cati*).

**Therapeutic group:** The medicine belongs to the antiparasitic group.

#### 4. CONTRAINDICATIONS:

##### Do not use the medicine:

- If the cat is sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine. The active ingredients are listed in section 2 and the additional ingredients are listed in section 13.
- If the cat is sick or suffers from seizures.
- In kittens weighing less than 0.6 kg or kittens younger than 7 weeks.
- Do not use in rabbits, hyraxes or dogs.

#### 5. SIDE EFFECTS:

As with any medicine, use of this medicine may cause side effects in some cats. Do not be alarmed when reading the list of side effects. The cat may not suffer from any of them.

Common side effects (occur in 1-10 in 100 cats) that have been observed in clinical trials:

- Temporary clumping and spiking of the fur at the application site of the medicine.
- Moderate and transient skin irritation (e.g., itching, hair loss) at the application site of the medicine.
- If the cat licks the application site of the medicine, temporary excessive salivation may occur.

Swallowing the medicine (also as a result of licking it) may cause side effects associated with the digestive system and/or the central nervous system, such as: vomiting, excessive salivation, ataxia, disorientation, apathy and pupil dilation, and in very rare instances (fewer than 1 in 10,000 cats): muscle tremors, transitory blindness or impaired vision.

These effects usually resolve on their own within 24 hours, but if they do not, bring the cat to the attending veterinarian for treatment. Applying the medicine in accordance with the detailed instructions for use (see section 8) will reduce the occurrence of these effects.

If one of the side effects worsens, or if the cat 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](http://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 SPECIES:

The medicine is intended for use in cats only.

#### 7. METHOD OF ADMINISTRATION AND DOSAGE FOR SPECIES:

Always use according to 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 dose.

The medicine should be used when the cat has or is suspected of having a mixed infestation of tapeworms (cestodes), roundworms (nematodes) and various external parasites (ectoparasites). If there is a single and not mixed infestation, treatment with a preparation suitable for the existing single infestation should be considered.

Do not extrapolate the treatment from one animal to another without a veterinarian's opinion.

**Method of administration:** For external use only. For application by dripping onto the cat's skin, at a place where fur is growing.

**Dosage:** The minimal dosage is 0.12 ml solution for every 1 kg cat body weight.

Dosage for a cat **weighing less than 2.5 kg**: applicator containing 0.3 ml solution.

Dosage for a cat **weighing 2.5 -7.5 kg**: applicator containing 0.9 ml solution. Dosage for a cat **weighing more than 7.5 kg**: a combination of two applicators as detailed above.

To prevent infestations with heartworm larvae (heartworm disease ; *Dirofilaria immitis*) – start treatment one month after suspected first exposure to mosquitoes which cause the disease.

For treatment against the *Aelurostrongylus abstrusus* strain of roundworms (nematodes) – a further administration one month after the initial treatment may be needed.

#### 8. HOW TO USE THE MEDICINE:

- Open the carton package and take out the tray.
- Using a pair of scissors, cut the tray along the dotted line and pull off the cover.
- Wear gloves while applying the medicine to the cat.
- Remove the applicator from the tray and hold it vertically (upward).
- Pull the plunger down a little, turn and remove the cap.
- Part the cat's fur near the shoulder blades region (in the back region, between the shoulders and head connection) **until the skin is exposed.**

- Place the applicator directly on the exposed skin and gently press until the entire content is emptied out in one spot.
- Wash your hands immediately after applying the medicine to the cat.

**How can you contribute to the success of the treatment?** Special notes for applying the medicine:

- In cats with long and/or dense fur – make sure to apply the medicine onto the skin.
- Make sure that the entire content of the applicator is emptied onto the skin.
- Apply to an area where the cat cannot lick the solution. Make sure that treated cats do not lick each other.
- Avoid allowing the cat to lick the solution; it is recommended not to allow it to groom its fur immediately after application.
- To achieve optimal efficacy, it is recommended not to wash or shampoo the cat for two days after the treatment. Short contact of the cat's fur with water up to twice a month does not detract from the efficacy of the medicine.
- After applying the medicine, ticks will generally die within 48 hours. However, the cat may become infested after administration of the medicine, and live ticks may therefore be found on the fur.
- Tapeworm infestation may occur if the living area is not treated simultaneously by extermination of fleas, mice, etc.
- Sometimes, parasites develop resistance to the medicine, especially following frequent use. Consult a veterinarian on this topic.
- Cats aged 6 months and above, who lived in areas affected by heartworm disease (*Dirofilaria immitis*), should be tested for existing heartworm infestation before administering preventative treatment with this medicine.
- To prevent reinfestation in a household with several animals, it is recommended that all cats and dogs in the household be treated with appropriate antiparasitic preparations. It is recommended to repeat treatment with the antiparasitic preparation periodically (in accordance with the instructions for use) to prevent reinfestation.
- It is also recommended to treat the cat's sleeping, resting and living spaces, including the cat bed, carpets and soft furniture. In case the cat has extensive parasitic infestation and when treatment of the cat is commenced, it is recommended to use suitable measures to cleanse these places, and then vacuum them regularly.

#### 9. WITHDRAWAL PERIOD:

**Withdrawal time before slaughter:** Irrelevant. The medicine is intended for cats only.

#### 10. WARNINGS:

- **Special warnings regarding use in the target animal:** To ensure maximal efficacy, it is important to ensure that the medicine is applied to the cat's skin, and avoid applying it to the fur. Do not administer the medicine orally and do not inject. Take care that the medicine does not come into contact with the cat's mucous membranes (eyes, nostrils, genitals, damaged skin). It is recommended not to bath the cat for two days after applying the medicine. The safety of the medicine has not been tested with frequency of application of less than two weeks, in kittens weighing less than 0.6 kg or in kittens younger than 7 weeks.
- **Special warnings regarding safety of the use of the medicine in animals:** Not known.
- **Special warnings regarding the safety of the person handling the medicine:** Do not smoke, eat or drink when applying the medicine. Use gloves when applying the medicine. Wash your hands with water and soap after applying the medicine. Avoid contact of the solution with the fingers, and in case of such contact, rinse with soap and water. In case of contact of the solution with the eyes or mucous membranes, such as the mouth and nose, flush thoroughly with running water. A treated cat should not be touched, especially not by children, until the treated area has dried. Do not allow sleeping or playing with the cat (especially not by children) until the treated area has dried. Avoid contact of the medicine with people sensitive (allergic) to the active ingredients or to any of the additional ingredients contained in the medicine. The active ingredients are listed in section 2 and the additional ingredients are detailed in section 13.
- **Additional warnings:** If the cat received an overdose or if a person has accidentally swallowed the medicine, refer immediately to the veterinarian, to the doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

- **Pregnancy and lactation:** The safety of use of the medicine in pregnant and lactating cats has not been established. In such cases, the treating veterinarian must weigh the risk versus benefit of use of this medicine.

- **Interactions with other medicines, and other forms of interactions:** Not known. If the cat is receiving, or has recently received, other medicines and other preparations (including preparations for treatment of external parasites), tell the veterinarian or pharmacist.

- **Overdose:** The safety of the medicine has been established in healthy kittens, aged 7 weeks and above, upon administration of doses 5 times greater than the maximum recommended dosage, who were treated up to 6 times at 4-week intervals.

In cases of overdose, transient, moderate side effects may occur, such as: ataxia, disorientation, apathy and pupil dilation. The effects pass on their own within about one day. Temporary salivation and/or vomiting may occur, in isolated cases.

Side effects were not observed in cats with heartworm infection treated 3 times every 4 weeks at dosages 3 times greater than the maximum recommended dosage, and the dosage was well tolerated.

- **Incompatibilities:** Not known.

#### 11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach 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. Keep in the original package to protect from light. Keep the applicator in its individual package. Store the remaining applicators, that have not been used, in their tray(s).
- **Storage after opening the applicator:** Use the applicator immediately after opening, and dispose of it immediately afterwards.

#### 12. INSTRUCTIONS REGARDING DISPOSAL OF THE MEDICINE/ REMNANTS OF THE MEDICINE AFTER USE:

- Do not discard the medicine into a pool, lake, water sources or water channels, as the medicine may endanger fish and aquatic animals.
- Do not discard the medicine into the toilet or household waste bin.
- Ask your pharmacist or veterinarian how to dispose of medicines that have expired or that are no longer necessary. These measures will help protect the environment.

#### 13. FURTHER INFORMATION:

- **In addition to the active ingredients, the medicine also contains the following inactive ingredients:** Butylhydroxytoluene (BHT ; E321), Dimethyl Isosorbide, Glycerol Formal, Disodium Edetate (E385), n-Propyl Gallate (E310), Thiodipropionic Acid.
- **What the medicine looks like and contents of the package:** The medicine appears as a clear colorless to yellow to red/brown solution. The solution is packaged in a syringe-shaped applicator. The volume of solution within is marked on the applicator and package.
- **Package size:** The medicine is provided in carton boxes containing tray(s) with 1, 3, 4, 6 or 15 individual applicators.
- The number of applicators in each carton box may differ between package size.
- The number of applicators in the package is indicated on the carton box.
- Not all package sizes may be marketed.
- **Registration holder:** Beit Erez Havat Milatin Ltd., P.O.B. 209, Mishmar Hashiva 5029700.
- **Manufacturer:** Boehringer Ingelheim Vetmedica GmbH, Ingelheim am Rhein, Germany.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:  
158-50-34520-00

**Revised in:** 03/2022 according to MOH guidelines.