

**הנדון: עדכון העלון לרופא והעלון לצרכן של התכשיר**  
**BROADLINE VETERINARY – ברודליין וטרינרי**  
**Fipronil, (S)-Methoprene, Eprinomectin and Praziquantel**  
**Spot-On Solution (Drops) for the skin of cats**

חברת בית ארז חוות מילטין בע"מ מבקשת להודיע על עדכון העלון לרופא והעלון לצרכן של התכשיר ברודליין וטרינרי – Broadline Veterinary. העדכון נעשה במסגרת הוספת התוויות חדשות לתכשיר ועדכונים בהנחיות.

בהודעה זו מצויינים העדכונים המהותיים בלבד בעלון לרופא ובעלון לצרכן. בעלון ישנם שינויים נוספים.

**התוויה הרשומה לתכשיר בישראל (התוויות קיימות והתוויות חדשות):**

For cats with, or at risk from mixed infestations by cestodes, nematodes and ectoparasites. The veterinary medicinal product is exclusively indicated when all three groups are targeted at the same time.

Ectoparasites:

- Treatment and prevention of infestations by fleas (*Ctenocephalides felis*). Elimination of fleas within 24 hours. One treatment prevents further infestations for at least one month.
- Prevention of environmental flea contamination by inhibiting the development of flea immature stages (eggs, larvae and pupae) for over a month.
- The product can be used as part of a treatment strategy for the control of flea allergy dermatitis (FAD).
- Treatment and prevention of infestations by ticks (*Ixodes ricinus*). Elimination of ticks within 48 hours. One treatment prevents further infestations for up to 3 weeks.
- Treatment of notoedric mange (*Notoedres cati*).

Cestodes:

- Treatment of infestations with tapeworms (*Dipylidium caninum*, *Taenia taeniaeformis*, *Echinococcus multilocularis*, *Joyeuxiella pasqualei* (adult), and *Joyeuxiella fuhrmanni* (adult)).

Nematodes:

- Treatment of infestations with gastrointestinal nematodes (L3, L4 larvae and adults of *Toxocara cati*, L4 larvae and adults of *Ancylostoma tubaeforme* and adults of *Toxascaris leonina* and *Ancylostoma braziliense*).
- Treatment of infestations with vesical worms (*Capillaria plica*).
- Prevention of heartworm disease (*Dirofilaria immitis* larvae) for one month.
- Treatment of infestations with feline lungworms (L3 larvae, L4 larvae and adults of *Aelurostrongylus abstrusus*, L4 larvae and adults of *Troglostrongylus brevior*).

**בעלי החיים להם מיועד התכשיר:**

CATS.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

**4.4 Special warnings for each target species:** When applying the veterinary medicinal product, special attention should be paid in long hair breeds in order to ensure that it is applied directly to the skin and not on the hair, as this could lead to a lower bioavailability of the active substances and thus, to a reduced efficacy.

No data on the effect of bathing / shampooing on the efficacy of the veterinary medicinal product in cats is available. However, brief contact of the animal with water on one or two occasions within the month following application is unlikely to significantly reduce its efficacy. As a precaution, it is not recommended to bathe animals within 2 days after topical treatment.

After treatment with BROADLINE VETERINARY, ticks will generally be killed within 48 hours after infestation without having a blood meal. However, since the attachment of single ticks after treatment cannot be excluded transmission of infectious diseases cannot be completely ruled out.

Tapeworm infestation may reoccur unless control of intermediate hosts such as fleas, mice etc. is undertaken.

In certain individual cats *Notoedres cati* infestation may be severe or complicated by bacterial infections. In these severe cases concomitant treatment may be necessary.

Parasite resistance to any particular class of antiparasitic drug may develop following frequent use of a compound of that class. Therefore, epidemiological information about current susceptibility of the target species should be taken into account in order to limit the possibility of a future selection for resistance.

Cats in areas endemic for heartworm, or those which have travelled to endemic areas, may be infected with adult heartworms. Although the veterinary medicinal product may be safely administered to cats infected with adult heartworms, no therapeutic effect against adult *Dirofilaria immitis* has been established. It is therefore recommended that all cats 6 months of age or more, living in areas endemic for heartworm, should be tested for existing adult heartworm infestation before being treated with the product for heartworm prevention.

Some cats with patent *Joyeuxiella spp.* infestation may nevertheless harbour a high proportion of juvenile worms, which are not susceptible to the product; therefore a post-treatment follow-up is recommended in case of such infestations. To reduce re-infestation from emergence of new fleas, it is recommended that all cats in a household be treated. Other animals living in the same household should also be treated with a suitable product.

All stages of fleas can infest the cat's basket, bedding and regular resting areas such as carpets and soft furnishings. In case of massive flea infestation and at the beginning of the control measures, these areas should be treated with a suitable environmental product and then vacuumed regularly.

#### **4.5 Special precautions for use:**

Special precautions for use in animals: Spot-on application only. Do not inject, do not administer orally or via any other route. Avoid contact with the cat's eyes.

It is important to apply the veterinary medicinal product to a skin area where the cat cannot lick it off: on the neck, in between shoulders. Avoid animals licking each other following treatment.



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Oral ingestion of the veterinary medicinal product resulted in common to uncommon vomiting, hypersalivation and/or in transient neurological signs such as ataxia, disorientation, apathy and pupil dilation in safety studies. Muscle tremors have been reported in very rare cases based on post marketing safety experience. These signs usually resolve spontaneously within 24 hours. On very rare occasions, symptomatic treatment can be required.

The safety of the veterinary medicinal product has not been tested at intervals of less than 2 weeks or in kittens weighing less than 0.6 kg and/or under 7 weeks of age. The product is not for use in kittens weighing less than 0.6 kg and/or under 7 weeks of age.

The veterinary medicinal product is not intended for use in dogs. Some dog breeds may present increased susceptibility to macrocyclic lactones, potentially leading to signs of neurotoxicity. Oral uptake by dogs, specifically by Collies, Old English Sheepdogs and related breeds or crossbreeds should thus be avoided.

Echinococcosis represents a hazard for humans, and is a notifiable disease to the World Organisation for Animal Health (OIE).

Special precautions to be taken by the person administering the veterinary medicinal product to animals: Do not smoke, drink or eat during application. Wear gloves when handling the veterinary medicinal product. Wash hands immediately after use. Unused applicators must be stored in the intact blister package.

Avoid contact of the applicator content with the fingers. If this occurs, wash off with soap and water. In case of accidental eye exposure, flush the eyes thoroughly with water as the product can cause slight mucous membrane and eye irritation. If eye irritation persists or if side effects are noted, seek medical advice and show the package leaflet or the label to the physician.

Handling of treated animals should be limited until the application site is dry. Children should not be allowed to play with treated animals during this period. Recently treated animals should not sleep with owners, especially children.

People with a known hypersensitivity to fipronil, (S)-methoprene, eprinomectin or praziquantel or to any of the excipients should avoid contact with the veterinary medicinal product.

**קיימים עדכונים נוספים. למידע נוסף יש לעיין בעלון לרופא ובעלון לצרכן המעודכנים.**

העלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום בית ארז חוות מילטין בע"מ, רח' האדום 6, אזור תעשייה כנות, כנות 7982501. טלפון: 08-6204070. דואר אלק': [info@milatin-group.co.il](mailto:info@milatin-group.co.il)

בברכה,

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