**Fluralaner** (Bravecto) Chews for Dogs

**Dosage Schedule**

- **Bravecto** 1-Month should be administered with food.
- **Dosage Schedule**
  - **Dogs**: 5.8 – 9.9 lbs
  - **Bravecto** 1-Month
  - **Administer**: 120 mg
- **Dogs** 10.1 – 22.0 lbs
  - **Bravecto** 1-Month
  - **Administer**: 240 mg
- **Dogs** 22.1 – 44.0 lbs
  - **Bravecto** 1-Month
  - **Administer**: 480 mg
- **Dogs** 44.1 – 88.0 lbs
  - **Bravecto** 1-Month
  - **Administer**: 720 mg

**Dosage Schedule**

- **Dogs 22.1 – 44.0 lbs**: 
  - **Bravecto** 1-Month
  - **Administer**: 240 mg
- **Dogs 44.1 – 88.0 lbs**: 
  - **Bravecto** 1-Month
  - **Administer**: 720 mg

**Indications**

- **Bravecto** 1-Month is indicated for the treatment and control of *Ctenocephalides felis* and *Ixodes Ricinus* infestations for one month in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.

**Dosage and Administration**

- **Bravecto** 1-Month should be administered as a single dose monthly according to the Bravecto Schedule below to provide a minimum dose of 4.4 mg/kg (fluralaner) for the entire month.
- **Bravecto** 1-Month should be administered with food.

**Precautions**

- **Fluralaner** is a member of the isoxazoline class. This class has been associated with excessive adrenocortical reactions including tremors, panting, and salivation. Seizures have been reported in dogs treated with isoxazoline compounds.
- **Bravecto** 1-Month is not effective against *American* or *Punjab* fleas in less than 4 months of age (beef)

**Description**

- **Bravecto** 1-Month is a flavored chew formulated to provide a minimum dose of 4.4 mg/kg (fluralaner) body weight of *felinus*

**Animal Safety**

- **Marginal of Safety Study**: In a range of safety study, Bravecto 1-Month was administered orally to beaged-old puppies at 1, 3, and 5X the recommended dose at three, 30-day intervals (Days 1, 31, and 61). The dogs in the high group were unvaccinated.

- There were no clinically-relevant, treatment-related effects on body weights, food consumption, urine output, hematology, C-reactive protein, coagulation profiles, urinalysis, gross and histopathology. Adverse events or clinical changes from the most common categories occurring at a similar incidence in the treated and control groups were noted at necropsy, with the exception of slightly increased numbers of drusen (pigmented epithelial cells) in the eye of female dogs in the treated groups. Vomiting was noted in one dog in the 1X treatment group post-dose on Day 61. Feces were noted in one dog in each of the 2 Bravecto dose groups on Day 3 and 4 days post-treatment.

**Not for Human Use**

- The product contains fluralaner, a member of the isoxazoline class. It is not for use in humans. Fluralaner is toxic if ingested, inhaled, or absorbed through the skin. Not for use in children. Keep the product in the original packaging until use.

**General Information**

- Fluralaner is the chemical name of fluralaner, the active ingredient in Bravecto 1-Month. Bravecto 1-Month kills adult fleas and is indicated for the treatment and control of flea infestations for one month in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.

- Bravecto 1-Month is also indicated for the treatment and control of *American* and *Punjab* fleas in dogs, cats, and other animals to prevent accidental ingestion of the active ingredient in Bravecto 1-Month, demonstrated effectiveness against *Lone Star Ticks* and *American Dog Ticks* for 1 month in dogs and 2 months in cats and other animals administered orally to 8-week old puppies at 1, 3, and 4 chews per package.

**Use in Pregnant or Lactating Animals**

- Fluralaner is a member of the isoxazoline class. This class has been associated with excessive adrenocortical reactions including tremors, panting, and salivation. Seizures have been reported in dogs treated with isoxazoline compounds.

- **Preclinical Studies**: The following abnormalities were noted in 7 pups from 2 of the 5 X fluralaner dose groups on Day 1 at 4 hours post-dose. Tremors were noted in one dog in the 1X treatment group post-dose on Day 61. Feces were noted in one dog in each of the 2 Bravecto dose groups on Day 3 and 4 days post-treatment. No additional seizures occurred during the study. One dog in the control group with a history of epilepsy developed activity 28 days after its first dose; the dog received its second dose later the same day. No additional seizures were observed from the concurrent use of Bravecto 1-Month with other medications, such as vaccines, in a well-controlled field study in dogs 8 weeks of age and older, and weighing 4.4 to 44.0 pounds.

- Vomiting was noted in one dog in the 5X group and one dog in the 1X group post-dose on Day 61. Tremors were noted in one dog in each of the 3 fluralaner dose groups on Day 1 at 4 hours post-treatment. No additional seizures were observed from the concurrent use of Bravecto 1-Month with other medications, such as vaccines, in a well-controlled field study in dogs 8 weeks of age and older, and weighing 4.4 to 44.0 pounds.

- During the palatability assessment, four dogs coughed within 72-hours after treatment or infestation for 31 days.
- In a well-controlled laboratory study conducted in households with existing flea infestations, the effectiveness of Bravecto 1-Month against fleas on Day 3, 7, 14, and 28 was compared with bebenzer 50% and pyriproxyfen 30% spot-on formulations. Bravecto 1-Month with a single dose of 4.4 mg/kg effectively controlled fleas for 28 days, a single dose of 8.8 mg/kg effectively controlled fleas for 56 days, and a single dose of 13.2 mg/kg effectively controlled fleas for 104 days.

- Fluralaner was administered orally to 8-week old puppies at 1, 3, and 5X the recommended dose at three, 30-day intervals (Days 1, 31, and 61). The dogs in the high group were unvaccinated. There were no clinically-relevant, treatment-related effects on the body weights, food consumption, reproduction, urinary, liver or renal function, or morphology. Adverse events or clinical changes from the most common categories occurring at a similar incidence in the treated and control groups were noted at necropsy, with the exception of slightly increased numbers of drusen (pigmented epithelial cells) in the eye of female dogs in the treated groups. Vomiting was noted in one dog in the 1X treatment group post-dose on Day 61. Feces were noted in one dog in each of the 2 Bravecto dose groups on Day 3 and 4 days post-treatment. No additional seizures occurred during the study. One dog in the control group with a history of epilepsy developed activity 28 days after its first dose; the dog received its second dose later the same day. No additional seizures were observed from the concurrent use of Bravecto 1-Month with other medications, such as vaccines, in a well-controlled field study in dogs 8 weeks of age and older, and weighing 4.4 to 44.0 pounds.

- Fluralaner is the chemical name of fluralaner, the active ingredient in Bravecto 1-Month. Bravecto 1-Month kills adult fleas and is indicated for the treatment and control of flea infestations for one month in dogs and puppies 6 months of age and older, and weighing 4.4 pounds or greater.

- Bravecto 1-Month is also indicated for the treatment and control of *American* and *Punjab* fleas in dogs, cats, and other animals to prevent accidental ingestion of the active ingredient in Bravecto 1-Month, demonstrated effectiveness against *Lone Star Ticks* and *American Dog Ticks* for 1 month in dogs and 2 months in cats and other animals administered orally to 8-week old puppies at 1, 3, and 4 chews per package.

- Use in Pregnant or Lactating Animals**: Fluralaner is a member of the isoxazoline class. This class has been associated with excessive adrenocortical reactions including tremors, panting, and salivation. Seizures have been reported in dogs treated with isoxazoline compounds.

- **Preclinical Studies**: The following abnormalities were noted in 7 pups from 2 of the 5 X fluralaner dose groups on Day 1 at 4 hours post-dose. Tremors were noted in one dog in the 1X treatment group post-dose on Day 61. Tremors were noted in one dog in each of the 3 fluralaner dose groups on Day 1 at 4 hours post-treatment. No additional seizures were observed from the concurrent use of Bravecto 1-Month with other medications, such as vaccines, in a well-controlled field study in dogs 8 weeks of age and older, and weighing 4.4 to 44.0 pounds.

- **Use in Pregnant or Lactating Animals**: Fluralaner is a member of the isoxazoline class. This class has been associated with excessive adrenocortical reactions including tremors, panting, and salivation. Seizures have been reported in dogs treated with isoxazoline compounds.