Fact Sheet for Pet Owners and Veterinarians about Potential Adverse Events Associated with Isoxazoline Flea and Tick Products

Fast Facts

- The FDA is alerting pet owners and veterinarians of the potential for neurologic adverse events in dogs and cats when treated with drugs that are in the isoxazoline class.
- Although these products can and have been <u>safely used</u> in the majority of dogs and cats, pet owners should consult with their veterinarian to review their patients' medical histories and determine whether a product in the isoxazoline class is appropriate for their pet.

What should I know?

- The FDA considers products in the isoxazoline class to be safe and effective for dogs and cats but is providing this information so that pet owners and veterinarians can take it into consideration when choosing flea and tick products for their pets.
- Isoxazoline products have been associated with neurologic adverse reactions, including muscle tremors, ataxia, and seizures in some dogs and cats;
- Although most dogs and cats haven't had neurologic adverse reactions, seizures may occur in animals without a prior history;
- Many products are available for prevention and control of flea and tick infestations. Some flea and tick products are <u>regulated by the FDA</u> and some are regulated by the Environmental Protection Agency. You can discuss all options with your veterinarian to choose the right product for your pet.

What products are in the isoxazoline class?

- The FDA-approved drugs in this class are
 - o Bravecto (fluralaner) tablets for dogs
 - o Bravecto (fluralaner) topical solution for cats and dogs
 - o Bravecto Plus (fluralaner and moxidectin) topical solution for cats
 - o Bravecto 1-month (fluralaner) tablets for dogs
 - Credelio (lotilaner) tablets for dogs and cats
 - Nexgard (afoxolaner) tablets for dogs
 - Simparica (sarolaner) tablets for dogs
 - Simparica Trio (sarolaner, moxidectin and pyrantel) tablets for dogs
 - o Revolution Plus (selamectin and sarolaner) topical solution for cats
- These products are approved for the treatment and prevention of flea infestations, and the treatment and control of tick infestations. Some are also approved for treatment and control of ear mite infestations and some gastrointestinal parasite infections, and a few are also approved for prevention of heartworm disease.

What should I do if my pet has an adverse drug event while using an isoxazoline product?

- If your dog or cat experiences any adverse event while using an isoxazoline product, first consult your veterinarian.
- The FDA continues to monitor adverse drug event reports for these products and encourages pet owners and veterinarians to report adverse drug events. You can do this by reporting to the drugs' manufacturers, who are required to report this information to the FDA, or by submitting a report directly to the FDA.
- To report suspected adverse drug events for these products and/or obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, contact the appropriate manufacturers at the following phone numbers:
 - o Merck Animal Health (Bravecto): 800-224-5318
 - o Elanco Animal Health (Credelio): 888-545-5973
 - o Boehringer Ingelheim (Nexgard): 888-637-4251
 - o Zoetis (Simparica, Revolution Plus): 888-963-8471
- If you prefer to report directly to the FDA, or want additional information about adverse drug experience reporting for animal drugs, see How to Report Animal Drug and Device Side Effects and Product Problems.
- Pet owners and veterinarians who have additional questions can contact <u>AskCVM@fda.hhs.gov</u> or call 240-402-7002.