

Whole Dog Journal

<https://www.whole-dog-journal.com/blog/Hold-Off-on-Those-Oral-Flea-Killing-Medications-21926-1.html>

Hold Off on Those Oral Flea-Killing Medications

The FDA has linked some flea control products to neurological damage in dogs and cats.

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Posted at 09:45AM

By [Nancy Kerns](#)

On September 20, the FDA issued a [communication](#) for pet owners and veterinarians, warning about the potential for neurologic adverse events following the administration of certain flea and tick products to dogs and cats. The products named in the release are oral products, available by veterinary prescription only, that contain isoxazoline-based ingredients. These include Bravecto, Credelio, Nexgard, and Simparica.

As [we described in September 2017](#), both Nexgard and Simparica have verbiage on their package inserts that say, “Use with caution in dogs with a history of seizures or neurologic disorders.” To date, Bravecto has not included this recommendation on its product insert, though we extended this warning to dog owners in our article, based on the fact that the active ingredients in the products use the same mode of action. [Credelio](#) is a newer drug, given market approval by the FDA in January 2018; its package insert does include the statement “Use with caution in dogs with a history of seizures.”

The FDA communication notes, “In the first three years after approval, the FDA pays particularly close attention to adverse event reports, looking for any safety information that may emerge.” In the case of the isoxazoline-based flea-killing medications, the FDA observed a significant number of “adverse drug experience” reports mentioning these medications and pets that experienced seizures. The FDA has asked the drug manufacturers to add information about this issue to their product labels, and encourages veterinarians to “use their specialized training to review their patients’ medical histories and determine, in consultation with pet owners, whether a product in the isoxazoline class is appropriate for the pet.”

The communication did not include any mention of flea-control medications that contain spinosyn-based ingredients (Comfortis or AcuGuard, and [Trifexis](#) or ComboGuard), which work in a very similar fashion to the isoxazolines. However, the package insert for these medications include the statement “Use with caution in dogs with pre-existing epilepsy.”

In light of this FDA communication, *Whole Dog Journal* would like to make the following recommendations:

1. If your dog has ever had a seizure, has a known seizure disorder, or is descended from a breed or family that is prone to developing seizures:

Do not administer to your dog any flea-control product that contains isoxazoline-based ingredients (Bravecto, Credelio, Nexgard, and Simparica) – OR products that contain spinosyn-based ingredients (Comfortis or AcuGuard, and Trifexis or ComboGuard).

2. Until more information is made available by the FDA about the relative risk being posed by these products, we'd hold off on giving ANY dog ANY of these oral flea medications.

An exception could *perhaps* be made for dogs who have severe flea allergy, live in an area where fleas are a constant threat, who suffer serious adverse reactions to [topical flea-killing pesticides](#), and who have taken these oral products previously without any adverse reactions. (Read carefully: That would encompass a very tiny pool of potential candidates.)

3. As we noted in our September 2017 article, oral products that kill fleas pose many disadvantages over topical flea-killing pesticides.

Most important is the fact that, once consumed, there is no way to reverse or neutralize their activity in case of an adverse reaction. In contrast, if a dog has an adverse reaction to a topical pesticide, the dog can be [thoroughly washed and re-washed](#) to reduce the product's absorption and shorten its effect on the dog.

4. The FDA did not include information about what specifically prompted the publication of its communication.

Has there been a spike in the number of reported cases of seizures among dogs (and cats) treated with these drugs? Or are the numbers of seizures being reported far greater than the pre-market approval studies led the FDA to expect? We have asked the FDA for this information and will report further as we learn more.

The following pages are from the FDA Website--here are the direct links:

<https://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm620934.htm>

<https://www.fda.gov/AnimalVeterinary/ResourcesforYou/AnimalHealthLiteracy/ucm620940.htm>

Here is a link to a table comparing various flea products. The table was created by a vet clinic in Los Angeles, CA.

<http://www.marvistavet.com/flea-product-comparison.pml>

Animal Drug Safety Communication: FDA Alerts Pet Owners and Veterinarians About Potential for Neurologic Adverse Events Associated with Certain Flea and Tick Products

September 20, 2018

The U.S. Food and Drug Administration is alerting pet owners and veterinarians to be aware of the potential for neurologic adverse events in dogs and cats when treated with drugs that are in the isoxazoline class.

Since these products have obtained their respective FDA approvals, data received by the agency as part of its routine post-marketing activities indicates that some animals receiving Bravecto, Nexgard or Simparica have experienced adverse events such as muscle tremors, ataxia, and seizures. Another product in this class, Credelio, recently received FDA approval. These products are approved for the treatment and prevention of flea infestations, and the treatment and control of tick infestations.

The FDA is working with manufacturers of isoxazoline products to include new label information to highlight neurologic events because these events were seen consistently across the isoxazoline class of products.

The FDA carefully reviewed studies and other data on Bravecto, Credelio, Nexgard and Simparica prior to approval, and these products continue to be safe and effective for the majority of animals. The agency is asking the manufacturers to make the changes to the product labeling in order to provide veterinarians and pet owners with the information they need to make treatment decisions for each pet on an individual basis. Veterinarians should use their specialized training to review their patients' medical histories and determine, in consultation with pet owners, whether a product in the isoxazoline class is appropriate for the pet.

Although FDA scientists carefully evaluate an animal drug prior to approval, there is the potential for new information to emerge after marketing, when the product is used in a much larger population. In the first three years after approval, the FDA pays particularly close attention to adverse event reports, looking for any safety information that may emerge.

The FDA monitors adverse drug event reports received from the public or veterinarians, other publicly available information (such as peer-reviewed scientific articles), and mandatory reports from the animal drug sponsor (the company that owns the right to market the drug). Drug sponsors must report serious, unexpected adverse events within 15 days of the event. In addition, they must submit any events that are non-serious, plus any laboratory studies, in vitro studies, and clinical trials that have not been previously submitted to the agency, on a bi-annual basis for the first two years following product approval and annually thereafter.

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:

Merck Animal Health (Bravecto): 800-224-5318

Elanco Animal Health (Credelio): 888-545-5973

Merial (Nexgard): 888-637-4251

Zoetis (Simparica): 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 Side Effects and Product Problems](#).

Additional Information

[Fact Sheet for Pet Owners and Veterinarians about Potential Adverse Events Associated with Isoxazoline Flea and Tick Products](#)

Contact FDA

240-402-7002

240-276-9115 FAX

Issued by: FDA, Center for Veterinary Medicine

7500 Standish Place, HFV-1

Rockville, MD 20855

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.
- The FDA-approved drugs in this class are Bravecto, Credelio, Nexgard and Simparica. These products are approved for the treatment and prevention of flea infestations, and the treatment and control of tick infestations.
- Although these products can and have been safely used 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. 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
 - Bravecto
 - Credelio
 - Nexgard
 - Simparica
- These products are approved for the treatment and prevention of flea infestations, and the treatment and control of tick infestations.

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:
 - Merck Animal Health (Bravecto): 800-224-5318
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- 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 Side Effects and Product Problems](#).
- Pet owners and veterinarians who have additional questions can contact AskCVM@fda.hhs.gov or call 240-402-7002.

Additional Information

[Animal Drug Safety Communication: FDA Alerts Pet Owners and Veterinarians About Potential for Neurologic Adverse Events Associated with Certain Flea and Tick Products](#)