

FDA-Approved Treatment Causes Reactions in 2 out of 3 Dogs

Even veterinarians routinely prescribe these based on an animal's history. But that could be a tragic mistake with this dangerous chemical. Seizures, tremors, lack of muscle control or death could occur, even if your dog has never had an adverse reaction in the past.

Analysis by [Dr. Karen Shaw Becker](#)

STORY AT-A-GLANCE

- In 2018, the FDA issued an alert for flea/tick products containing the chemical insecticide isoxazoline due to the potential for neurologic adverse events in dogs and cats
- Project Jake, a large-scale survey of veterinarians and pet owners regarding the use of isoxazoline-containing flea/tick products, wrapped up around the same time; the survey results were published in June of this year
- According to the Project Jake survey results, of 1,594 dogs given a flea treatment (1,325 of which contained isoxazoline), 66.6% experienced an adverse event, including muscle tremors, ataxia (loss of muscle control), seizures and death
- Reports of adverse events connected to flea/tick products should give every pet parent pause
- Whenever possible, consider using safe, nontoxic alternatives to protect your pet from pests

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In 2018, the U.S. Food and Drug Administration (FDA) issued an alert to pet owners and veterinarians about the potential for neurologic adverse events in dogs and cats treated with flea and tick products containing isoxazoline, a parasiticide (chemical insecticide).¹ In 2019, the alert was updated to include two additional products.

The quite serious side effects pets have experienced after being given products containing isoxazoline include muscle tremors, ataxia (loss of muscle control), and seizures. The implicated products have received FDA approval and include:

- Bravecto (fluralaner) tablets for dogs
- Bravecto (fluralaner) topical solution for cats and dogs
- Nexgard (afoxaloner) tablets for dogs
- Simparica (sarolaner) tablets for dogs
- Credelio (lotilaner) tablets for dogs
- Revolution Plus (selamectin and sarolaner topical solution) for cats

The FDA has asked the manufacturers of these products to change the 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."

The agency also suggests that, "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."

I'm guessing most veterinarians who routinely prescribe chemical flea/tick products would only consider pets with a previous history of neurologic issues to be at risk. After all, there's no way to predict a potential problem in healthy animals, and yet the FDA warns that, "... seizures may occur in animals without a prior history."² You can find information on additional potentially toxic flea/tick chemicals here.

Project Jake Pet Owner and Veterinarian Survey

While the FDA doesn't provide specifics in its alert about adverse events, "Project Jake," a pet owner and veterinarian online survey about flea and tick medications containing isoxazoline was wrapping up at around the same time the alert was issued in 2018. The survey findings involved 2,751 respondents and were released in June 2020.³

According to veterinarian Dr. Jean Dodds, one of the co-authors of the study, the Project Jake survey was broadly based and included:⁴

- People who didn't give their pets any flea or tick medications
- Pet parents who didn't observe any adverse reactions as well as those that did report them, providing a more inclusive review of isoxazoline use
- Observations by pet owners pre- (3 months) and post-drug use
- Questions when an adverse event occurred after use of the drug
- Questions about number of doses of drug(s) given before an adverse event
- Other concurrent health issues and treatments given
- Multiple adverse events
- Recovery information and/or follow-ups

It's also important to note that the survey ended before the FDA alert was released, so the results represent an objective review.

66% of Dogs Given a Flea Treatment Suffered an Adverse Event

Of the 2,751 Project Jake survey responses (all involving dogs), 42% (1,157) reported no flea treatment or adverse events, 58% (1,594) reported that a pet had been treated with a flea control parasiticide, and of those, 83% (1,325) received a product containing isoxazoline. Of the 1,594 dogs given any flea treatment, 66.6% had an adverse event (AE).

The Project Jake survey findings were compared to findings of the FDA and the European Medicines Agency (EMA). The number of total adverse events reported to the FDA and EMA were comparable, but there was a 7 to 10 times higher incidence of seizures and deaths reported by the EMA or from outside the U.S.

Serious adverse events involving neurological effects, seizures and deaths in the Project Jake findings were higher than the FDA but somewhat lower than the EMA reports. In addition, the number of reported deaths and seizures associated with flea treatments containing lotilaner and spinosad in the Project Jake results were considerably higher than product labelling suggests with regard to potential neurological effects.

The Project Jake study co-authors also raise concerns about human exposure to isoxazoline, as well as exposure through the food chain. From the study:

"Based on the results from the Project Jake survey and reviews of publicly available FDA and EMA AE reports demonstrating that cross-species neurotoxicity exists, the following issues also require further attention: Recognition of human exposure risk as delineated in package inserts, and concerns that may arise from recent proposals to repurpose isoxazoline veterinary drugs for application to vector-borne human diseases by treating humans (Miglianico et al., 2018).

Furthermore, there is a very real potential for food-chain associated AE, since fluralaner (as Exzolt) has recently been approved for treatment in poultry in Europe (Exzolt fluralaner for chickens)⁵."

The position of the Project Jake study co-authors is that as a class of drugs, isoxazolines "can work as intrinsic neurotoxins across species." In addition:

"The data also suggested notable differences in reporting of AE for the US versus European territories. This may reflect cultural tendencies and/or procedural methodologies for reporting of AE.

Nevertheless, the national and international post-market safety survey data summarized here indicate an immediate need for continued cross-species studies and a critical review of product labelling by regulatory agencies and manufacturers. Moreover, this class of drugs had more serious AE than those reported in the package inserts.

We believe that the FDA should consider additional changes to their criteria for AE observation, and define what would be needed for future clearances of this class of drugs."

You can find the full Project Jake survey results [here](#).

Safe, Nontoxic Alternatives to Chemical Parasiticides

While it's true that some pets are given chemical flea/tick preventives regularly for a lifetime and have no observable adverse reactions, the volume of reports of negative outcomes connected to these products should have every pet parent asking, "Is it worth the risk?" In the majority of cases, my answer is no, and my advice is to exhaust all possible nontoxic alternatives first. Some I recommend include:

- A safe, natural DIY pest deterrent (see recipe below)
- Cedar oil (specifically manufactured for pet health)
- Natural, food-grade diatomaceous earth, topically (avoid eyes, nose and mouth)

- Fresh garlic (¼ teaspoon of freshly chopped garlic per 15 pounds of body weight)
- Feed a nutritionally optimal, species-appropriate fresh food diet to bolster your pet's innate immune defenses
- Bathe and brush your pet regularly and perform full-body inspections to check for parasite activity (if you spend a lot of time outdoors, it's important to check your pet and yourself for ticks every night during tick season)
- Use a flea and tick comb to naturally exfoliate your pet's skin while removing or exposing pests (absolutely nothing takes the place of physically checking for ticks)
- Make sure both your indoor and outdoor environments are unfriendly to pests

All-Natural Homemade Pest Deterrents

- **For dogs** — You can actually make an all-natural pest deterrent for your dog very easily at home. It will help him avoid a good percentage of the pests he encounters, though not all of them. The recipe: mix 8 ounces of pure water with 4 ounces of organic, unfiltered apple cider vinegar and 20 drops of neem oil.

Neem oil is not an essential oil. It's an expelled or pressed oil, and it's safe for cats (I have a pest deterrent recipe for kitties I'll give you in a second). Neem oil is effective because fleas and ticks hate it. It's also great for animals who are very sensitive to smells.

Catnip oil can also be used as a pest deterrent, since it has been proven to be as effective as diethyltoluamide (DEET), the mosquito and tick spray humans use that has a number of toxic side effects.

If you want to add some extra punch to your dog's pest recipe, go with an extra five drops of lemon, lemongrass, eucalyptus, or geranium oil. I use geranium oil quite a bit because I find it very effective. In fact, I use it in my Dr. Mercola natural flea and tick products. If you have a dog who comes in contact with ticks, adding the extra punch of one of the essential oils I listed can be very beneficial.

You can store your homemade pest deterrent in the fridge, which is what I do. Before my dogs head out in the morning, I mist them with it, being careful to avoid their eyes. The active ingredients, especially the oils in the recipe, dissipate in about four hours, so you may need to reapply it several times throughout the day.

- **For cats** — My recipe for cats is very similar to the one for dogs. Mix 8 ounces of pure water with 4 ounces of organic, unfiltered apple cider vinegar, plus 10 drops of neem oil and 10 drops of catnip oil. Cats and essential oils can be tricky, so we want to leave essential oils out of the kitty recipe.

Neither neem nor catnip oil are truly essential oils - they're distillates, so we're safe using those. Catnip oil works to deter mosquitoes as well. Cats aren't prone to heartworm, which is a mosquito-borne disease, but dogs are.

So those are two easy, all-natural recipes you can use to deter pests and as a bonus, they also make your dog or cat smell wonderful! You can use them during flea season, tick season, and all summer long and feel good that you're not using pesticides on your pet.

If you live in areas where pests are such a problem you have to use chemicals, consider starting with the spinosad class of chemicals, which are derived from soil bacteria, and whenever you use chemicals, make sure to detox your pet simultaneously.

Sources and References

^{1,2} [FDA.gov](#)

³ [Palmieri, V. et al. Survey of canine use and safety of isoxazoline parasiticides. Veterinary Medicine and Science, June 2, 2020](#)

⁴ [Dr. Dodds: Flea and Tick Medications: Adverse Event Findings Released by Project Jake, August 10, 2020](#)

⁵ [European Medicines Agency, Exzolt \(fluralaner\)](#).
