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保存年限：

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附件：如主旨1081471528-A1

主旨：美國食品藥物管理署(FDA)對異噁唑啉類(isoxazoline class)部分防跳蚤及壁蝨產品，可能於部分犬貓發生神經性副作用提出警示(如附)，請惠予轉知所屬及獸醫師(佐)依據專業判斷，使用前揭產品時，應與飼主詳盡說明，請查照。

說明：

- 一、相關產品在核准上市前，本局已詳細審查關於產品之毒理安全、效果等研究數據，這些產品對大多數動物仍是安全有效，此結果與FDA聲明相同。
- 二、查FDA警示產品在我國登記資料如下：
 - (一)Bravecto (fluralaner) tablets for dogs，中文藥品名稱為一錠除，台灣英特威動物藥品股份有限公司登記核准。
 - (二)Nexgard (afoxalaner) tablets for dogs，中文藥品名稱全能狗咀嚼錠，台灣百靈佳般格翰動物事業股份有限公司登記核准。
 - (三)Simparica (sarolaner) tablets for dogs，中文藥品名稱寵愛食剋，臺灣碩騰股份有限公司登記核准。

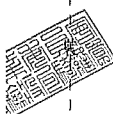
三、有關我國核准許可證資訊，可至本局動物用藥品資訊服務網查詢(<https://amdrug.baphiq.gov.tw/Animal/AMItem4.aspx>)

正本：中華民國獸醫師公會全國聯合會、社團法人臺北市獸醫師公會、社團法人新北市獸醫師公會、社團法人高雄市獸醫師公會、高雄縣獸醫師公會、桃園市獸醫師公會



師公會、新竹市獸醫師公會、新竹縣獸醫師公會、苗栗縣獸醫師公會、社團法人臺中市獸醫師公會、彰化縣獸醫師公會、南投縣獸醫師公會、雲林縣獸醫師公會、嘉義市獸醫師公會、嘉義縣獸醫師公會、社團法人臺南市獸醫師公會、屏東縣獸醫師公會、宜蘭縣獸醫師公會、花蓮縣獸醫師公會、臺東縣獸醫師公會、基隆市獸醫師公會、澎湖縣獸醫師公會、金門縣獸醫師公會、臺灣動植物防疫檢疫暨檢驗發展協會

副本：基隆市動物保護防疫所、桃園市政府動物保護處、新竹市動物保護及防疫所、苗栗縣動物保護防疫所、南投縣政府農業處、嘉義市政府建設處、臺南市政府農業局、屏東縣動物防疫所、宜蘭縣政府農業處、臺東縣政府農業處、宜蘭縣動植物防疫所、新北市政府動物保護防疫處、新竹縣家畜疾病防治所、南投縣家畜疾病防治所、臺北市動物保護處、臺中市動物保護防疫處、彰化縣動物防疫所、雲林縣動植物防疫所、嘉義縣家畜疾病防治所、高雄市動物保護處、花蓮縣動植物防疫所、澎湖縣家畜疾病防治所、金門縣動植物防疫所、本局動物防疫組



局長馮海東

IN THIS SECTION

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

Update:**April 22, 2019**

This posting was updated on April 22, 2019 to include another recently approved product in the isoxazoline class, Revolution Plus (selamectin and sarolaner topical solution).

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 (fluralaner) tablets for dogs, Bravecto (fluralaner) topical solution for cats and dogs, Nexgard (afoxaloner) tablets for dogs, or Simparica (sarolaner) tablets for dogs, have experienced adverse events such as muscle tremors, ataxia, and seizures. Two additional products in this class, Credelio (lotilaner) tablets for dogs and Revolution Plus (selamectin and sarolaner topical solution) for cats, recently received FDA approval. These products are approved for the treatment and prevention of flea infestations, and the treatment and control of tick infestations. Revolution Plus, is also approved for prevention of heartworm disease, treatment and control of ear mite infestations and some gastrointestinal parasite infections.

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. Revolution Plus, which was approved most recently, includes the new labeling information to highlight the potential for neurologic events in the isoxazoline class, and Merial has made the requested changes to Nexgard's labeling including adding the new class statement.

The FDA carefully reviewed studies and other data on Bravecto, Bravecto Topical, Credelio, Nexgard, Simparica and Revolution Plus 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, 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 Side Effects and Product Problems \(/animal-veterinary/report-problem/how-report-animal-drug-side-effects-and-product-problems\)](#).

Additional Information

Fact Sheet for Pet Owners and Veterinarians about Potential Adverse Events Associated with Isoxazoline Flea and Tick Products ([/animal-veterinary/animal-health-literacy/fact-sheet-pet-owners-and-veterinarians-about-potential-adverse-events-associated-isoxazoline-flea](#))

Issued by FDA Center for Veterinary Medicine.
For questions, Contact CVM (</about-fda/center-veterinary-medicine/contact-cvm>).

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