**Simparica Safety Summary**

**Data from March 2016 through December 2017**

The safety profile of Simparica® (sarolaner) Chewables has been well established through pre-approval

laboratory and field safety studies and the continuous evaluation of adverse drug event reports, also

known as pharmacovigilance (PV) data.

SIMPARICA HAS A PROVEN TRACK RECORD OF SAFETY

Since the launch of Simparica in March 2016, its use has been steadily increasing.

* Simparica has been used in thousands of veterinary hospitals with millions of doses sold worldwide.
* The adverse event profile continues to be predictable and consistent with the label and pre-

approval studies.

* The most common clinical signs reported are vomiting, lethargy, and diarrhea. All clinical signs

coded in these cases were reported as very rare (defined as less than 1 report per 10,000 doses

administered).

CHOOSING SIMPARICA FOR YOUR PRACTICE

* Simparica provides you with a quality flea and tick product backed by extensive scientific data.
* A single Simparica chewable offers safe, monthly flea and tick protection for dogs that starts working fast and remains effective for 35 days 1.
* Plus, Simparica allows you to offer your clients a premium product without the premium price

tag helping you to compete with over-the-counter products.

IMPORTANT SAFETY INFORMATION: Simparica is for use only in dogs, 6 months of age and older.

SIMPARICA may cause abnormal neurologic signs such as tremors, decreased conscious proprioception,

ataxia, decreased or absent menace, and/or seizures. Simparica has not been evaluated in dogs that are

pregnant, breeding or lactating. Simparica has been safely used in dogs treated with commonly

prescribed vaccines, parasiticides and other medications. The most frequently reported adverse

reactions were vomiting and diarrhea. See full Prescribing Information, attached.

References: Six RH, Everett WR, Young DR, et al. Efficacy of a novel oral formulation of sarolaner ;(Simparica TM) against five common tick species infesting dogs in the United States. Vet Parasitol. 2016;222:28 -32

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**FDA Announcement on Isoxazoline Class Labeling**

**Frequently Asked Questions**

Why is the FDA mandating this label update for all isoxazoline products?

The FDA published an Animal Drug Safety Communication on September 20, 2018 to alert pet owners and veterinarians to be aware of the potential for neurologic adverse events in animals when treated with drugs that are in the isoxazoline class. As reported in the communication, since the first isoxazoline products on the market obtained their respective FDA approvals, data received by the FDA as part of its routine post-marketing activities indicates that some animals receiving these products experienced adverse events such asmuscle tremors, ataxia, and seizures. The FDA-approved drugs in this class are Bravecto, Credelio, Nexgard and Simparica.The FDA carefully reviewed studies and other data on Bravecto, Credelio, Nexgard and Simparica prior to their respective approvals, andthe FDA reminds pet owners and veterinarians that these products continue to be safe and effective for most animals.

Why is this information being released by the FDA now?

As reported in the recent Animal Drug Safety Communication on September 20, 2018, 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 agency has been collecting post-marketing data on all isoxazoline products since their respective approvals that indicates some animals receiving Bravecto, Nexgard or Simparica have experienced adverse events such as muscle tremors, ataxia, and seizures. These events were seen consistently across the isoxazoline class of products. Another product in this class, Credelio, recently received FDA approval. In addition, prior to the release of the recent FDA announcement, the labels for each isoxazoline product noted some information about neurologic signs either in their “Precautions” or “Animal Safety” section. We believe following the FDA’s announcement this information will be reflected consistently across labels.