



Important information about RILEXINE® (cephalexin) Chewable Tablets

March 19, 2019

Dear Doctor and Staff:

This letter is to inform you that, because RILEXINE® Chewable Tablets are designed to taste good, Virbac is adding informational and precautionary language to the label and package outsert leaflet. This action is being taken after noting a number of adverse event reports where pets accidentally ingested overdoses of tablets and at the request of FDA. Fortunately, no fatalities have been reported in association with these accidental overdose cases. The clinical signs seen with these adverse events have usually been short-lived and related to gastrointestinal signs. Thus, the following labeling changes were made:

The following Precautions section was added to the DOSAGE AND ADMINISTRATION section on the bottle labels:

Precautions: RILEXINE® Chewable Tablets are designed to taste good. Store RILEXINE Chewable Tablets out of reach of dogs, cats and other pets in a secured location (See Product Insert for complete information).

The following statements were added to the first paragraph of the PRECAUTIONS section of the product outsert following the first sentence:

RILEXINE® Chewable Tablets are designed to taste good. Store RILEXINE Chewable Tablets out of reach of dogs, cats and other pets in a secured location. Post approval experience has shown that dogs and cats may willingly consume more than the recommended dosage of RILEXINE Chewable Tablets which can result in overdose. Adverse reactions may occur if large quantities of tablets are ingested (see Adverse Reaction, Animal Safety and Information for Dog Owners sections). If the product is dispensed in a container other than the original, prescribers should consider adding a statement on the bottle label reminding the owner that RILEXINE Chewable Tablets are designed to taste good and should be stored out of reach of pets in a secured location.

The following information about reporting adverse drug events was added at the end of the ADVERSE REACTIONS section on the product outsert:

To report suspected adverse drug events and/or obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, contact Virbac at 1-800-338-3659. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

The following INFORMATION FOR DOG OWNERS section was added after the ADVERSE REACTIONS section of the product outsert:

Information for Dog Owners

*Owners should be advised that RILEXINE® Chewable Tablets are designed to taste good. Owners should be instructed to keep the product in a secured storage area out of reach of pets in order to prevent accidental ingestion or overdose. Post approval experience has shown that dogs and cats may willingly consume more than the recommended dosage of RILEXINE Chewable Tablets. Adverse reactions may occur if large quantities of tablets are ingested (see **Precautions, Adverse Reactions and Animal Safety sections**).*

Owners should be advised to contact their veterinarian immediately and notify Virbac (1-800-338-3659) if the dog ingests more tablets than prescribed or if other pets ingest RILEXINE Chewable Tablets. In the case of accidental ingestion by humans, contact a physician immediately.

With the implementation of these label changes, we ask that you:

- **Please read and become familiar with the new label for RILEXINE Chewable Tablets.**
- **Please add wording regarding secure storage of this product by pet owners to your dispensing labels as noted above (if not routinely on your dispensing label).**
- **Please counsel the pet owners for which you dispense RILEXINE Chewable Tablets that the medicine is designed to taste good and therefore should be securely stored to prevent accidental ingestion, potential overdosing, and potential adverse effects.**

Thank you for trusting Virbac products. As always, if you have any **medical questions** regarding RILEXINE Chewable Tablets, please call Virbac Veterinary Technical Product Support at **1-800-338-3659**. Our veterinary technicians and veterinarians are available to address any medical questions or concerns you may have.

Virbac remains committed to shaping the future of animal health by providing quality products such as this.

Respectfully,



Frank Hurtig, DVM
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