

May 23, 2011

Dear Doctor:

Novartis Animal Health US, Inc. strives to inform veterinary professionals about important prescribing instructions for patients and clients. With that in mind, we would like to share with you an update about the product label for CAPSTAR® (nitenpyram) tablets, the flea adulticide for cats and dogs.

Product labels are living documents that are revised periodically based on post-marketing experience, including adverse drug events that are voluntarily reported to the drug sponsor or Food and Drug Administration (FDA) by clinics, pet owners and others. All pharmacovigilance reports received by Novartis Animal Health, regardless of relative frequency, seriousness or causality, are forwarded to the FDA for review. As growing numbers of animals receive established products such as CAPSTAR tablets (used safely and effectively for over a decade with an estimated 50 million doses distributed), additional information is gleaned and evaluated.

Based on this body of knowledge, Novartis Animal Health has made changes to the CAPSTAR package insert. They include additional guidance to help minimize the risk of future adverse events, such as reinforcing the important message that CAPSTAR tablets are intended for use in dogs and cats that are, at a minimum, **2 pounds in weight and 4 weeks old**, and a new section on clinical signs observed in post-approval adverse event reports, reproduced below:

*“The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse reactions are reported to FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using this data. The following adverse events are listed in decreasing order of reporting frequency.*

*“CATS: Hyperactivity, panting, lethargy, itching, vocalization, vomiting, fever, decreased appetite, nervousness, diarrhea, difficulty breathing, salivation, incoordination, seizures, pupil dilation, increased heart rate, and trembling.*

*“DOGS: Lethargy/depression, vomiting, itching, decreased appetite, diarrhea, hyperactivity, incoordination, trembling, seizures, panting, allergic reactions including hives, vocalization, salivation, fever, and nervousness.*

***“The frequency of serious signs, including neurologic signs and death, was greater in animals under 2 pounds of body weight, less than 8 weeks of age, and/or reported to be in poor body condition. In some instances, birth defects and fetal/neonatal loss were reported after treatment of pregnant and/or lactating animals.”***

The Post-Approval Experience section is also referenced in “Other Information,” as in “CAPSTAR tablets are safe for pregnant or nursing dogs and cats (See Post-Approval Experience section).”

Currently, the product label notes that dogs and cats treated with CAPSTAR tablets may temporarily scratch as fleas begin to die. The behavior (commonly referred to as the “tickle effect”) is a reaction to the moribund fleas, not the drug. Per the updated label, “In cats and dogs, this may present as transient signs of hyperactivity, panting, vocalization and excessive grooming/licking.” These signs also appear in the new Post-Approval Experience section.

The CAPSTAR label refers to a Flea Management System for dogs and cats, where the previously listed clinical signs from Post-Approval Experience are repeated (per respective species).

Novartis Animal Health encourages veterinarians to report suspected adverse events and provides contact information in the revised label to facilitate this process.

To make a report or request technical assistance concerning a Novartis Animal Health product, please call 1-800-637-0281. Events can also be reported directly to the FDA at 1-800-FDA-VETS or <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm>.

Changes to the CAPSTAR product label described in this letter are applicable now. Due to production factors, clinics may notice a delay of approximately eight months until revised product literature is available. Meanwhile, please share this information with associates in your practice, and call Novartis Animal Health at 1-800-637-0281 if you have questions or concerns about CAPSTAR tablets or any of our products.

Sincerely,

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