

COMFORTIS® and ivermectin interaction Safety Warning Notification
June 24, 2008

Today the U.S. Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) is announcing that it has received reports of adverse reactions in dogs receiving the drug Comfortis® (spinosad) concurrently with high, extra-label doses of the drug ivermectin. The clinical signs of these adverse reactions are consistent with ivermectin toxicity.

Comfortis® (spinosad), manufactured by Elanco Animal Health, a division of Eli Lilly and Company, is a monthly oral, chewable tablet used for the prevention and treatment of flea infestations on dogs. Veterinarians who use high, extra-label doses of ivermectin to treat dogs with non-responsive demodectic mange and other conditions should be aware that some dogs have developed signs of ivermectin toxicity when ivermectin is used concurrently with Comfortis® (spinosad).

CVM and Elanco Animal Health are advising veterinarians that dogs receiving extra-label doses of ivermectin should not receive concurrent treatment with Comfortis® (spinosad).

CVM is working with Elanco Animal Health as they address this issue. Additional information regarding this safety warning can be obtained on the Elanco Animal Health website.

Lilly Companion Animal Health Technical Bulletin: Spinosad and the Extra-Label Use of High Dose Ivermectin for the Treatment of Generalized Demodicosis in Dogs. FDA Site.