Boehringer Ingelheim

Dear Doctor,

Since we last updated you in January on the ongoing supply disruptions of VETMEDIN® (pimobendan) in the U.S. market, we have continued to pursue a number of pathways to help increase available supply. Due to complexities at the production site, including impacts from COVID-19, we are continuing to experience insufficient supply of this critical product in the treatment of canine heart failure.

Both Boehringer Ingelheim Animal Health and the Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) recognize the serious medical need for VETMEDIN. As part of our efforts to help remediate the supply disruptions of VETMEDIN in the U.S, and with the cooperation of FDA's Center for Veterinary Medicine, Boehringer Ingelheim Animal Health will import on a temporary basis two VETMEDIN products used in Canada and the United Kingdom.

Boehringer Ingelheim will begin temporarily importing VETMEDIN capsules as well as VETMEDIN chews. We anticipate distribution of the imported product may begin in May 2021. Boehringer Ingelheim Animal Health's FDA-approved site in Mexico will also continue to manufacture VETMEDIN chewable tablets for the U.S. market. This means that there will be three presentations of VETMEDIN (pimobendan) in the U.S. market throughout the year, and possibly at the same time: VETMEDIN capsules, VETMEDIN chews, and the current FDA approved VETMEDIN chewable tablets.

Although there are differences in the labeling, all three products contain the same active ingredient, pimobendan. Our field, technical services and other personnel will work closely with veterinary clinics to understand labeling differences so veterinarians can ensure appropriate dosing for each canine patient. Technical product specifications will be included with each shipment of product for clinic use, as well as pet owner specific information sheets.

As always, we recommend you report any suspected adverse events following the use of the imported VETMEDIN capsules or VETMEDIN chews, or the FDA-approved VETMEDIN chewable tablets. Please include in your report the lot number of the product potentially associated with any suspected adverse event.

To report a suspected adverse drug event (side effect) or a product quality problem contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251, option 1, then option 4. Adverse drug events and product quality problems may also be reported directly to FDA by completing the online form available at http://www.fda.gov/reportanimalae or by requesting a hard copy of the form at 1-888-FDA-VETS.

We are hopeful that the measures we are taking will alleviate some of the supply constraints and disruption in the near term, while we are implementing longer-term solutions for addressing VETMEDIN supply.

Sincerely,

Shawn Hooker
Head of Pet Business
Boehringer Ingelheim Animal Health