Dear Veterinarian Letter notifying veterinarians about adverse events reported in dogs treated with Librela (bedinvetmab injection)

https://www.fda.gov/animal-veterinary/product-safety-information/dear-veterinarian-letter-notifying-veterinarians-about-adverse-events-reported-dogs-treated-librela

Dear Veterinarian,

The U.S. Food and Drug Administration's Center for Veterinary Medicine has completed an evaluation of adverse events reported in dogs of various ages treated with Librela (bedinvetmab injection). The adverse events identified and analyzed include: ataxia, seizures, other neurologic signs, including but not limited to, paresis, recumbency, urinary incontinence; polyuria, and polydipsia. In some cases, death (including euthanasia) was reported as an outcome of these adverse events. The FDA is making available reports containing summaries of clinical signs reported for Librela in the CVM FOIA Electronic Reading Room.

Drug Information

The FDA approved Librela, a monoclonal antibody drug used for the control of pain associated with osteoarthritis in dogs, on May 5, 2023, and it was introduced to the marketplace later that year. Prior to approval, the FDA reviewed available studies and other data on Librela and determined Librela to be safe and effective for its intended use for control of pain associated with osteoarthritis in dogs. Librela is dosed by weight and labeled for subcutaneous injection once a month.

What should a veterinarian do if a patient treated with Librela has an adverse event?

If a dog under your care experiences an adverse event while receiving Librela, the FDA encourages you to report it to Zoetis, the drug sponsor, at 1-888-963-8471. Drug sponsors are required to submit reports of adverse drug events to FDA. If you prefer to report directly to FDA, please see www.fda.gov/reportanimalae.

When reporting adverse events to the FDA and/or Zoetis, please include, if available, a full medical history, how many times the dog has received Librela, and the lot number on the vial used.

Where can veterinarians get more information about the adverse events that have been reported to the FDA?

The FDA is posting reports containing adverse drug event information for Librela on a rolling basis in the CVM FOIA Electronic Reading Room. If the agency has additional information to share, it will be made available.

Additional Information

The FDA monitors the safety profile of all animal drugs after they reach the market, as widespread use of a drug in a large number of patients may uncover adverse events not observed prior to approval. Pharmaceutical companies (drug sponsors) are required to report all cases of adverse events they receive from the public, including pet owners and veterinarians, to the FDA. The agency evaluates adverse events and other safety information when it becomes available. When appropriate, FDA works with the drug sponsor to address any concerns. FDA may request updates to drug labeling, post-

approval studies, or require additional or more frequent reporting. The FDA Center for Veterinary Medicine does not currently have the authority to mandate safety-related labeling changes.

For more information on drug sponsor's responsibilities to report adverse events, see Post-approval Animal Drug Reporting Requirements.

The FDA also makes available Animal Drug Safety-Related Labeling Changes on a regular basis. Please see the button on the page to subscribe to email updates.

The FDA's Center for Veterinary Medicine (CVM) is committed to promoting and protecting animal health by ensuring marketed animal drugs are safe and effective. For more information, please contact AskCVM@fda.hhs.gov.

Sincerely,

FDA's Center for Veterinary Medicine