Further information relating to VMD news item for Librela Solution for Injection in Dogs

15 January 2025

Overall incidence rating

The overall incidence of suspected adverse reactions for Librela Solution for Injection for Dogs (across all strengths since first authorised) is considered uncommon using the following standardised convention: - very rare (less than 1 animal in 10,000 animals, including isolated reports) - rare (more than 1 but less than 10 animals in 10,000 animals) - uncommon (more than 1 but less than 10 animals in 1,000 animals) - common (more than 1 but less than 10 animals in 100 animals) - very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment).

Important information for veterinary surgeons

We would like to highlight to veterinary professionals the below important information regarding recommended use of the product which is included within the Summary of Product Characteristics (SPC) in sections 4.3 Contraindications, 4.4 Special warnings for each target species, section 4.5 Special precautions for use and section 4.8 Interaction with other medicinal products and other forms of interaction:

- The product should not be used in cases of hypersensitivity to the active substance or to any of the excipients, in dogs under 12 months, in animals intended for breeding and in pregnant or lactating animals.
- The product may induce transient or persistent anti-drug antibodies. The induction of such antibodies is uncommon and may have no effect or may result in a decrease in efficacy in animals that responded to treatment previously. If no or limited response is observed within one month after initial dosing, an improvement in response may be observed after administration of a second dose one month later. However, if the animal does not show a better response after the second dose, the veterinary surgeon should consider alternative treatments.
- Where a dog has not been able to properly exercise prior to treatment due to its clinical condition, it is recommended that the dog is gradually (over a few weeks) allowed to increase the amount of exercise they take (to prevent overexercise by some dogs).
- There are no safety data on the concurrent long-term use of NSAIDs and bedinvetmab in dogs.
- In clinical trials in humans, rapidly progressive osteoarthritis has been reported in patients receiving humanised anti-NGF monoclonal antibody therapy. The incidence of these events increased with high doses and in those human patients that received long-term (more than 90 days) non-steroidal anti-inflammatory drugs (NSAIDs) concomitantly with an anti-NGF monoclonal antibody. Dogs have no reported equivalent of human rapidly progressive osteoarthritis.

The veterinary surgeon and the client should discuss and agree a specific treatment programme for an individual animal. This should be based on the clinical needs of the animal, balanced with the potential risks as outlined in the product information.