



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Librela (*bedinvetmab*)

An overview of Librela and why it is authorised in the EU

What is Librela and what is it used for?

Librela is a veterinary medicine used for the alleviation of pain associated with osteoarthritis in dogs. It contains the active substance bedinvetmab.

How is Librela used?

Librela is a solution for injection to be given subcutaneously (under the skin); the recommended dose depends on the dog's weight, and is given once a month. The medicine can only be obtained with a prescription.

For more information about using Librela, see the package leaflet or contact your veterinarian or pharmacist.

How does Librela work?

The active substance in Librela is bedinvetmab, a monoclonal antibody (a type of protein) designed to recognise and attach to a protein called nerve growth factor (NGF). Once attached, it prevents NGF from attaching to its receptors (targets) on nerve cells and interrupts the transmission of pain signals. This helps to bring relief from pain.

What benefits of Librela have been shown in studies?

Two field studies were conducted to show Librela's effectiveness.

The first study involved 287 dogs of various breeds in the EU. All dogs had osteoarthritis and either received Librela or placebo (a dummy treatment). The main measure of effectiveness was the pain score 28 days after treatment, assessed by owners, using a so-called Canine Brief Pain Inventory (CBPI). Additionally, veterinarians assessed the weight-bearing ability of dogs, the pain when dogs' limbs were touched or moved, and the general condition of the dogs in terms of mobility.

The results showed improvement in pain score in 43.5% of dogs treated with Librela compared with 16.9% in dogs given placebo. The examinations by veterinarians also showed significant improvements in the Librela-treated group compared to the placebo group.

In the second field study, conducted in the USA, 135 dogs were treated with Librela and 137 dogs



received placebo. Treatment success was achieved in 47.4% of Librela-treated dogs compared with 36.6% of dogs given placebo.

What are the risks associated with Librela?

The most common side effects with Librela (which may affect more than 1 but less than 10 animals in 1,000 animals treated) are mild injection site reactions (e.g. swelling and heat).

For the full list of side effects and restrictions of Librela, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

Safety information has been included in the summary of product characteristics and the package leaflet for Librela, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

Hypersensitivity reactions, including anaphylaxis, could potentially occur in the case of accidental self-injection. Repeated self-administration may increase the risk of hypersensitivity reactions.

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

Why is Librela authorised in the EU?

The European Medicines Agency decided that Librela's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Librela

Librela received a marketing authorisation valid throughout the EU on 10 November 2020.

Further information on Librela can be found on the Agency's website:
ema.europa.eu/medicines/veterinary/EPAR/librela.

This overview was last updated in 04-2021.