EMA/143616/2021
EMEA/V/C/005179

Solensia (*frunevetmab*)

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

What is Solensia, and what is it used for?

Solensia is a veterinary medicinal product, which contains the active substance frunevetmab. It is used in cats to relieve pain associated with osteoarthritis.

For more information, see the package leaflet.

How is Solensia used?

The medicine can only be obtained with a prescription.

Solensia is a solution for injection for cats. It is to be given subcutaneously (under the skin); the recommended dose is 1 to 2.8 mg/kg bodyweight, once a month.

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

How does Solensia work?

The active substance in Solensia is frunevetmab, a felinised monoclonal antibody (a type of cat-specific protein) designed to recognise and attach to a protein called nerve growth factor (NGF), which is involved in the regulation of pain. When frunevetmab binds to NGF, it prevents the bound NGF from attaching to its receptors on nerve cells where it regulates pain signalling. This way, it helps relieve pain associated with osteoarthritis.

What benefits of Solensia have been shown in studies?

Solensia was investigated in three field studies, a main one and two exploratory studies. All the studies were conducted in veterinary practices in the USA.

The pivotal field trial included 275 otherwise healthy cats with clinical signs of osteoarthritis in at least two joints or spinal segments, which showed pain. The cats received either the recommended dose (1 to 2.8 mg/kg bodyweight) of Solensia or a placebo (dummy treatment) once a month for three months.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

The main measure of treatment success was a pain score (on a scale of 3 to 15) assessed by owners, using a standard rating scale known as Client-Specific Outcome Measures (CSOM). CSOM rates a cat's response to pain treatment by looking at the cat's physical activity, sociability and quality of life.

Around 76% of cats who received frunevetmab had a successful treatment (defined as a reduction of at least 2 points in the total CSOM score and no increase in any individual score). This compares with 65% of cats who received placebo.

What are the risks associated with Solensia?

The most common side effects with Solensia (which may affect up to 1 in 10 animals) are skin reactions (itching, skin inflammation and hair loss).

Solensia should not be used in cats under 1 year of age or weighing less than 2.5 kg. It is also not for cats intended for breeding or cats that are pregnant or nursing kittens. For the full list of restrictions, 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 Solensia, 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 accidental self-administration may increase the risk of hypersensitivity reactions. Pregnant women, women trying to conceive, and breastfeeding women should take extreme care to avoid accidental self-injection. In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

Why is Solensia authorised in the EU?

The main study showed that Solensia was effective at reducing pain in cats with osteoarthritis, and the side effects are manageable. The European Medicines Agency therefore decided that Solensia's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Solensia

Solensia received a marketing authorisation valid throughout the EU on 17 February 2021.

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

This overview was last updated in 04-2021.