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Adtralza (*tralokinumab*)

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

What is Adtralza and what is it used for?

Adtralza is a medicine for treating adults with moderate to severe atopic dermatitis (also known as eczema, when the skin is itchy, red and dry). It is used in patients for whom treatment applied directly to the skin cannot be used or is not sufficient.

Adtralza contains the active substance tralokinumab.

How is Adtralza used?

Adtralza is available as a solution for injection under the skin. For atopic dermatitis, the first dose is four injections of 150 mg, each into a different location. This is followed by two injections of 150 mg every two weeks. The medicine can only be obtained with a prescription. For more information about using Adtralza, see the package leaflet or contact your doctor or pharmacist.

How does Adtralza work?

Patients with atopic dermatitis produce high levels of proteins called interleukin 13 (IL-13), which can cause inflammation of the skin leading to the symptoms of this disease such as redness, swelling and itching. The active substance in Adtralza, tralokinumab, is a type of protein (monoclonal antibody) designed to neutralise IL-13. By neutralising IL-13, tralokinumab prevents IL-13 from working and thereby reduces the inflammation and patient's symptoms.

What benefits of Adtralza have been shown in studies?

Adtralza was more effective than a placebo (dummy treatment) at reducing the extent and severity of atopic dermatitis after 16 weeks of treatment in three main studies in patients with moderate to severe disease that had not responded well enough to treatment applied to the skin. The main measures of effectiveness were having clear or almost clear skin, and a reduction in symptom score of at least 75%.

In the first study, which involved 802 patients, around 16% of patients who received Adtralza had clear skin or almost clear skin compared with 7% of those who received placebo. Symptoms were

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

satisfactorily reduced in 25% of patients who received Adtralza, compared with some 13% of those who received placebo.

In the second study, involving 794 patients, treatment with Adtralza led to clear or almost clear skin in about 22% of patients, compared with around 11% of patients who used a placebo. Symptoms were satisfactorily reduced in 33% of patients receiving Adtralza versus about 11% of those receiving placebo.

In the third study, 380 patients were given Adtralza or placebo, both in combination with a topical corticosteroid (a medicine for inflammation applied to the skin). Adtralza treatment led to clear or almost clear skin in around 39% of patients versus 26% of those receiving placebo. Symptoms were satisfactorily reduced in 56% of the patients who received Adtralza, compared with about 36% of patients on placebo.

What are the risks associated with Adtralza?

The most common side effects with Adtralza are upper respiratory tract infections (colds and other infections of the nose and throat) which may affect more than 1 in 10 people. Other common side effects include reactions at the injection site and redness and discomfort in the eye (which may affect up to 1 in 10 people). For the full list of side effects and restrictions, see the package leaflet.

Why is Adtralza authorised in the EU?

Three main studies have shown that Adtralza is effective at clearing the skin and reducing symptoms of atopic dermatitis. The side effects are considered manageable. The European Medicines Agency decided that Adtralza's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Adtralza?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Adtralza have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Adtralza are continuously monitored. Side effects reported with Adtralza are carefully evaluated and any necessary action taken to protect patients.

Other information about Adtralza

Adtralza received a marketing authorisation valid throughout the EU on 17 June 2021

Further information on Adtralza can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/adtralza

This overview was last updated in 08-2021.