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Adtralza® (active substance: tralokinumab)

First authorisation in Switzerland: 24 February 2022

Medicinal product (pre-filled syringe) for the treatment of moderate to severe atopic dermatitis (neurodermatitis) in adults

About the medicinal product

Adtralza contains the active substance tralokinumab and is used for the treatment of adult patients with moderate to severe atopic[1] dermatitis (also known as atopic eczema or neurodermatitis).

Atopic dermatitis is an inflammatory disease of the top layers of the skin triggered by various causes and which typically manifests as a red, very itchy rash. Up to 20% of children and up to 8% of all adults are affected by atopic dermatitis. Most cases involve mild forms that can be well controlled with locally applied topical products such as skin ointments. But more severe forms that can additionally require costly treatments with possible serious side effects also exist.

Therefore, Adtralza is used only when treatment with conventional, locally applied topical medicinal products is unable to control the disease adequately or cannot be used.

Mode of action

The active substance in Adtralza, tralokinumab, is a monoclonal antibody, a protein which, in turn, detects and binds to certain other proteins in the body. One feature of atopic dermatitis is an increase in the concentration of interleukin-13 (IL-13) in the body. Tralokinumab binds to IL-13 and thereby prevents it from generating and maintaining the inflammation in the skin.

[1] Atopy: Atopy refers to an allergic hypersensitivity to otherwise harmless natural and synthetic substances in the environment.

Use

Adtralza is a prescription-only medicine and is authorised as a pre-filled syringe containing 150 mg of the active substance tralokinumab. Adtralza is injected under the skin. The patient and the doctor then jointly decide whether the patient can self-administer the injections after corresponding instruction.

The recommended initial dose is 600 mg (four 150 mg injections), followed by 300 mg every two weeks.

Other topical preparations are usually prescribed in combination with Adtralza for the treatment of atopic dermatitis.

Efficacy

The efficacy of Adtralza in the treatment of atopic dermatitis was investigated in three studies with a total of over 1,900 adult patients with at least moderate disease that was not adequately controlled by topical treatment (studies: ECZTRA 1, ECZTRA 2 and ECZTRA 3).

The studies lasted 52 weeks (ECZTRA 1 and 2) and 32 weeks (ECZTRA 3). In all three studies, the patients received an initial dose of 600 mg Adtralza or a placebo (dummy drug without an active substance), followed by 300 mg every two weeks.

The severity of atopic dermatitis is determined by scores achieved on rating scales (e.g. IGA and EASI). The corresponding improvements in the scores were also used to confirm the effect in the clinical trials. The pivotal studies showed that the treatment with Adtralza produced an improvement in the atopic dermatitis (statistically significant improvement in the scores) compared to the treatment with placebo. A faster improvement in the appearance of the skin and the itching was also achieved.

Precautions, undesirable effects & risks

Adtralza must not be used in those who are hypersensitive to the active substance or any of the excipients.

As a result of the mode of action of Adtralza, the body's own immune system[2] may be inhibited during long-term treatment with this medicinal product. The use of Adtralza should be avoided in patients with a serious infection. Before starting treatment with Adtralza, it should be checked whether important vaccinations are up to date. If necessary, these should be given before starting treatment with Adtralza.

The most common undesirable effects occurring in all patients treated with Adtralza were upper respiratory tract infections (mainly common colds, but also e.g. cases of sinusitis or rhinitis).

Adtralza can cause serious side effects, which must be reported to the doctor without delay (e.g. breathing problems, swelling of the face, mouth and tongue, weakness, dizziness, feeling light-headed, skin rash and itching).

Treatment with Adtralza should be discontinued if no improvement is visible after 16 weeks at the latest.

All precautions, risks and other possible undesirable effects are listed in the Information for patients (package leaflet) and

[2] Immune system: the body's defence system against foreign substances and organisms

the Information for healthcare professionals.

Why the medicinal product has been authorised

The completed studies showed a benefit for Adtralza, compared to placebo, in the treatment of atopic dermatitis in adults with at least moderate disease that cannot be adequately controlled by local, topical measures (e.g. skin ointments).

Based on all the available data, the benefits of Adtralza outweigh the risks if used correctly in appropriately selected patients. Swissmedic has therefore authorised the medicinal product Adtralza for the treatment of adult patients with at least moderate atopic dermatitis when locally applied topical medicinal products are unable to control the disease adequately or cannot be used.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Adtralza®

Information for patients (package leaflet): Information for patients Adtralza®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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