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EPAR summary for the public

Dupixent

dupilumab

This is a summary of the European public assessment report (EPAR) for Dupixent. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Dupixent.

For practical information about using Dupixent, patients should read the package leaflet or contact their doctor or pharmacist.

What is Dupixent and what is it used for?

Dupixent is a medicine used to treat adults with moderate to severe atopic dermatitis (also known as atopic eczema, when the skin is itchy, red and dry).

Dupixent contains the active substance dupilumab.

How is Dupixent used?

Dupixent is available as pre-filled syringes containing 300 mg dupilumab in a solution for injection under the skin usually in the thigh or belly. The first dose is two injections of 300 mg in two different sites. This is followed by one injection every two weeks.

The doctor will consider stopping treatment if the condition does not show any improvement after 16 weeks.

Dupixent can only be obtained with a prescription and treatment should be started by a doctor who has experience in the diagnosis and treatment of atopic dermatitis. Patients or their carers may inject the medicine if their doctor or nurse considers it appropriate.

For further information, see the package leaflet.

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How does Dupixent work?

Patients with atopic dermatitis produce high levels of proteins called interleukin 4 and interleukin 13 (IL-4 and IL-13) which are involved in the disease. The active substance in Dupixent, dupilumab, is a monoclonal antibody (a type of protein) designed to block receptors (targets) for IL-4 and IL-13. By blocking the receptors, dupilumab prevents IL-4 and IL-13 from working and relieves the symptoms of the disease.

What benefits of Dupixent have been shown in studies?

Dupixent was more effective than placebo (a dummy treatment) at reducing the extent and severity of atopic dermatitis in 3 main studies in patients with moderate to severe disease. In the first study, which involved 740 patients, participants were given Dupixent or placebo, both in combination with a topical corticosteroid (a medicine for inflammation applied to the skin). Dupixent or placebo was used on its own in the other two studies involving a total of 1,379 patients.

After 16 weeks of treatment, 39% of patients treated with Dupixent every two weeks in the first study showed clearing or almost clearing of their atopic dermatitis compared with 12% of patients on placebo. Taking the results of the other two studies together, 37% of patients treated with Dupixent every two weeks had clearing or almost clearing of their atopic dermatitis compared with 9% of patients on placebo.

What are the risks associated with Dupixent?

The most common side effects with Dupixent are injection-site reactions (such as redness, swelling and itching), conjunctivitis (red, itchy eye with sticky pus), blepharitis (inflammation of the eyelid) and cold sores.

For the full list of all side effects and restrictions with Dupixent, see the package leaflet.

Why is Dupixent approved?

Dupixent has been shown to reduce the extent and severity of atopic dermatitis in patients with moderate to severe disease, for whom available therapies are limited. Regarding safety, Dupixent's side effects are generally mild and manageable.

The European Medicines Agency therefore decided that Dupixent's benefits are greater than its risks and recommended that it be approved for use in the EU.

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

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

Other information about Dupixent

The European Commission granted a marketing authorisation valid throughout the European Union for Dupixent on 27 September 2017.

The full EPAR for Dupixent can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about

treatment with Dupixent, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2017.