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Dupixent (*dupilumab*)

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

What is Dupixent and what is it used for?

Dupixent is a medicine used to treat patients aged 12 years or over with moderate to severe atopic dermatitis (also known as atopic eczema, when the skin is itchy, red and dry).

Dupixent is also used to treat severe asthma in patients aged 12 years or over whose asthma is not properly controlled by a combination of high-dose corticosteroids taken by inhalation plus another medicine used for the prevention of asthma. Dupixent is only for use in patients with a type of inflammation of the airways called 'type 2 inflammation'.

Dupixent contains the active substance dupilumab.

How is Dupixent used?

Dupixent is available as pre-filled syringes containing 200 mg or 300 mg dupilumab in a solution for injection under the skin, usually in the thigh or belly.

For atopic dermatitis, the first dose in adults and adolescents weighing 60 kg or more is two injections of 300 mg in two different sites. This is followed by one 300 mg injection every two weeks. In adolescents weighing less than 60 kg, the 200-mg injection is used. The doctor will consider stopping treatment if the condition does not show any improvement after 16 weeks.

For severe asthma, in patients taking corticosteroids by mouth or patients who also have atopic dermatitis, the first dose is two injections of 300 mg in two different sites. This is followed by one 300 mg injection every two weeks..

For all other asthma patients, the first dose is two injections of 200 mg in two different sites. This is followed by one 200-mg injection every two 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 the conditions Dupixent is used to treat. Patientsor their carers may inject the medicine themselves if their doctor or nurse considers it appropriate. The medicine is for long-term use and the need to continue taking the medicine should be assessed by the doctor at least yearly.

For more information about using Dupixent, see the package leaflet or contact your doctor or pharmacist.

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

How does Dupixent work?

Patients with atopic dermatitis and patients with asthma produce high levels of proteins called interleukin 4 and interleukin 13 (IL-4 and IL-13), which can cause inflammation of the skin and airways leading to the symptoms of these diseases. 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 disease symptoms.

What benefits of Dupixent have been shown in studies?

Atopic dermatitis

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.

A further study was carried out in 251 adolescents aged from 12 to less than 18 years with moderate to severe atopic dermatitis. In this study, after 16 weeks atopic dermatitis had cleared up or almost cleared up in around 24% of those given Dupixent every 2 weeks compared with around 2% of those given placebo.

Asthma

Dupixent was shown to reduce the number of exacerbations (flare-ups) of asthma during treatment in 2 main studies involving patients with asthma that was not adequately controlled by a combination of high-dose inhaled corticosteroids and other medicines. In the first study, involving 1,902 patients, the number of severe flare-ups per year was 0.46 in patients taking 200 mg Dupixent and 0.52 in patients taking 300 mg Dupixent, compared with 0.87 or 0.97 in patients given placebo. After 12 weeks of treatment, Dupixent improved patients' FEV_1 (the maximum volume of air a person can breathe out in one second) by 320 ml (for 200 mg Dupixent) or 340 ml (for 300 mg Dupixent) compared with 180 ml and 210 ml for placebo.

The second study, involving 210 patients, showed that in 70% of patients given Dupixent their condition improved to the extent that they could reduce their dose of corticosteroids taken by mouth compared with 42% of those given placebo.

What are the risks associated with Dupixent?

The most common side effects with Dupixent when used in treatment of atopic dermatitis are injection-site reactions (such as redness, swelling and itching),which may affect more than 1 in 10 people, and conjunctivitis (redness and discomfort in the eye), blepharitis (inflammation of the eyelid) and cold sores, which may affect up to 1 in 10 people. There have been very rare cases of serum sickness (allergy to foreign proteins) and serum sickness-like reactions.

The most common side effect with Dupixent when used in treatment of asthma is redness at the site of injection. Anaphylaxis (sudden, severe allergic reaction) has been reported very rarely.

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

Why is Dupixent authorised in the EU?

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. In the treatment of asthma, Dupixent has been shown to reduce the number of asthma flare-ups and the need for oral corticosteroid treatment. 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 it can be authorised 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.

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

Other information about Dupixent

Dupixent received a marketing authorisation valid throughout the EU on 27 September 2017.

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

This overview was last updated in 07-2019.