EMA/496462/2024
EMEA/H/C/004390

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:

- moderate to severe atopic dermatitis (also known as atopic eczema, when the skin is itchy, red and dry) in patients aged 12 years and over when topical treatments (treatments applied to the skin) are not sufficient or appropriate. Patients from 6 months up to 12 years of age can also be given the medicine if their condition is severe;
- severe asthma in patients aged 6 years and over whose asthma is not properly controlled by appropriate combination therapy (corticosteroids taken by inhalation plus another medicine used for the prevention of asthma). Dupixent is added to maintenance treatment and is only for use in patients with a type of inflammation of the airways called 'type 2 inflammation';
- chronic (long-term) obstructive pulmonary disease (COPD), a disease that causes breathing difficulties due to airway obstruction and damage to the lungs. Dupixent is used in adults who have increased levels of eosinophils (a type of white blood cell) and whose disease is not controlled well enough with a combination of a long-acting beta-2 agonist, a long-acting muscarinic agonist and an inhaled corticosteroid (other COPD medicines), or a combination of the first two if an inhaled corticosteroid is not appropriate. It is used with other medicines as maintenance (regular) treatment;
- inflammation of the nose and sinuses together with growths (polyps) obstructing the airways in the nose (chronic rhinosinusitis with nasal polyposis). It is used in adults in addition to local treatment with corticosteroids when other treatments have not worked well enough;
- moderate-to-severe prurigo nodularis (a long-term skin disease with a rash causing lumps with intense itching) in adults. It is used with or without topical (applied to the skin) corticosteroids;
- eosinophilic oesophagitis (an allergic inflammatory condition of the foodpipe) in adults and children from 1 year of age and weighing at least 15 kg, who cannot take conventional treatment or for whom it is not working;
- moderate to severe chronic spontaneous urticaria, an itchy rash that occurs without an obvious trigger. It is used in patients aged 12 years and over in whom treatment with antihistamines does not work well enough and who have not received medicines targeting immunoglobulin E (IgE).

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Dupixent contains the active substance dupilumab.

How is Dupixent used?

Dupixent is available as pre-filled pens or syringes containing dupilumab in a solution for injection under the skin, usually in the thigh or belly. Dupixent should be taken every week, every other week or every 4 weeks depending on the patient's age and weight, and the condition being treated. Depending on the dose, the medicine is given either as 1 or 2 injections in 2 different sites.

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. Patients or their carers may inject the medicine themselves if their doctor or nurse considers it appropriate and once they have been trained to do so. The medicine is for long-term use and the need to continue taking the medicine should be assessed by the doctor regularly.

Dupilumab can be used with or without topical corticosteroids.

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

How does Dupixent work?

Patients with atopic dermatitis, some types of asthma, COPD, chronic rhinosinusitis with nasal polyposis, prurigo nodularis, eosinophilic oesophagitis and chronic spontaneous urticaria produce high levels of proteins called interleukin 4 and interleukin 13 (IL-4 and IL-13). This can cause inflammation of the skin, airways and oesophagus, 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 adults 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. 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 study was also 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.

A further study involved 367 children between 6 and 12 years of age with severe atopic dermatitis in whom medicines applied to the skin had proved insufficient or were unsuitable. After 16 weeks,

measures of severity showed that atopic dermatitis had cleared up or almost cleared up in around 33% of those given Dupixent with a topical corticosteroid compared with around 11% of those given placebo with a corticosteroid.

In addition, a study involving children between 6 months and less than 6 years of age with moderate to severe dermatitis showed that a 16-week treatment with Dupixent and a topical corticosteroid led to skin clearing in 28% of patients (23 out of 83 patients) compared with 4% of patients (3 out of 79 patients) given placebo and a topical corticosteroid. Overall, 53% of patients (44 out of 83 patients) treated with Dupixent and a corticosteroid had an improvement in their skin of at least 75% compared with at least 11% (8 out of 11 patients) with placebo and a corticosteroid.

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 aged 12 years or above, 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) and 340 ml (for 300 mg Dupixent) compared with 180 ml and 210 ml for placebo.

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

A subsequent third study involved 408 children 6 to 11 years of age with severe asthma that was not adequately controlled by a combination of medium-to-high-dose inhaled corticosteroids and other medicines. It showed that the number of severe flare-ups of asthma per year was 0.31 in those with type 2 inflammation given Dupixent compared with 0.75 in similar children given placebo. After 12 weeks of treatment Dupixent improved patients' predicted FEV_1 by 10.5% compared with 5.3% in those given placebo.

COPD

Two main studies showed that Dupixent reduced the number of moderate or severe exacerbations (worsening) of COPD in a 1-year period.

The studies involved over 1,800 adults with COPD that was not adequately controlled with a combination of a long-acting beta-2 agonist, a long-acting muscarinic agonist and an inhaled corticosteroid, or a combination of the first two if an inhaled corticosteroid was not appropriate. These people also had raised blood levels of eosinophils. The studies compared the effect of Dupixent with that of placebo, both given in addition to the person's maintenance treatment. In the first study, patients given Dupixent had 0.78 COPD exacerbations per year, compared with 1.1 for patients who received placebo. In the second study, these figures were 0.86 for patients taking Dupixent and 1.3 for those given placebo.

The two studies also found that Dupixent improved patients' lung function, as measured by FEV_1. After one year of treatment, Dupixent improved FEV_1 by 153 ml and 115 ml, compared with 70 ml or 54 ml for placebo.

Chronic rhinosinusitis with nasal polyposis

Adding Dupixent to treatment with a corticosteroid nasal spray has been shown to improve symptoms of the condition more than placebo in 2 main studies as measured by scoring systems for the extent of nasal polyps and patients' perception of nasal congestion. In the first study, involving 276 adults, after around 6 months nasal polyp score fell by 1.89 with Dupixent and increased by 0.17 with placebo. Similarly, patients' score for nasal congestion fell by 1.34 with Dupixent versus 0.45 with placebo. In the second study, involving 448 adults, the polyp score fell by 1.71 with Dupixent and increased by 0.10 with placebo, and the congestion score fell by 1.25 versus 0.38, respectively.

Prurigo nodularis

Dupixent was more effective than placebo at reducing the extent and severity of itching caused by prurigo nodularis in 2 main studies involving a total of 311 adults with moderate to severe disease. The studies measured improvements in symptoms of itching using the Worst Itch Numeric Rating Scale (WI-NRS).

After 24 weeks of treatment, 59% of patients treated with Dupixent had a significant improvement in their symptoms (as measured by a reduction of at least 4 points in the WI-NRS) compared with 19% of patients on placebo.

Eosinophilic oesophagitis

In a study of 321 adults and adolescents from 12 years of age with eosinophilic oesophagitis, Dupixent was more effective than placebo in reducing oesophageal inflammation. In this study, more patients treated with Dupixent had low levels of eosinophils in their blood (a sign of reduced inflammation) compared with patients who had placebo. Patients treated with Dupixent also had greater improvements in their symptom scores for swallowing difficulties.

Another study involving 102 children from 1 year of age with eosinophilic oesophagitis showed that, after 16 weeks of treatment, Dupixent was more effective than placebo in reducing oesophageal inflammation: 43 out of 68 patients given Dupixent had low levels of eosinophils in their blood, compared with 1 out of 34 patients given placebo. This effect was maintained after 52 weeks of continued treatment with Dupixent.

Chronic spontaneous urticaria

Dupixent was investigated in two main studies involving a total of 289 patients from 12 years of age with chronic spontaneous urticaria who did not respond well enough to antihistamines and did not previously receive anti-IgE medicines. Dupixent was compared with placebo, when added to the patients' usual antihistamine treatment. The main measure of effectiveness was based on the change in disease activity after treatment, as measured on a scale ranging from 0 (no urticaria) to 42 (severe urticaria) called Urticaria Activity Score over 7 days (UAS7). After 24 weeks of treatment, patients who took Dupixent had a greater reduction in itch and hives than patients who took placebo. The UAS7 score in the first study was reduced by an average of 20.5 points in people who received Dupixent, compared with an average of 12.0 points in those who received placebo. In the second study, the score was reduced by 15.9 for Dupixent, compared with 11.2 for placebo.

What are the risks associated with Dupixent?

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

The most common side effects with Dupixent (which may affect up to 1 in 10 people) include injection site reactions (such as redness, swelling due to fluid build-up, itching and pain), conjunctivitis (redness

and discomfort in the eye) including conjunctivitis due to allergy, joint pain, cold sores and increased blood levels of a type of white blood cell called eosinophils. Additional side effects include injection site bruising in people with eosinophilic oesophagitis and those with COPD, as well as induration (hardening)and dermatitis (itchy, red and dry skin) at the injection site in people with COPD and chronic spontaneous urticaria. In addition, rash at the site of injection was reported in patients with COPD and haematoma (a collection of blood under the skin or in a muscle) at the site of injection in those with chronic spontaneous urticaria.

There have been very rare cases of serum sickness (allergy to the proteins in the medicine) and serum sickness-like reactions, anaphylaxis (sudden, severe allergic reactions) and ulcerative keratitis (inflammation and damage to the clear layer at the front of the eye) with Dupixent.

Why is Dupixent authorised in the EU?

Dupixent has been shown to reduce the extent and severity of atopic dermatitis and prurigo nodularis in patients with moderate to severe disease, for whom available therapies are limited. Similarly, in chronic rhinosinusitis with nasal polyposis, Dupixent produced clinically meaningful improvements in symptoms. Dupixent was also shown to be an effective treatment option for chronic spontaneous urticaria based on results of studies showing a reduction in the severity of symptoms in patients. The European Medicines Agency noted that data on use beyond 6 months are limited for chronic spontaneous urticaria and the need for continued therapy after 6 months of treatment should be regularly assessed. In the treatment of type 2 inflammatory asthma, Dupixent has been shown to reduce the number of asthma flare-ups and the need for oral corticosteroid treatment. In the treatment of eosinophilic oesophagitis, Dupixent has been shown to reduce eosinophilic inflammation. Dupixent has also been shown to reduce the number of moderate or severe exacerbations of COPD and improve lung function in patients with raised eosinophils in the blood and whose disease cannot be adequately controlled with available medicines.

Regarding safety, Dupixent's side effects are generally mild and manageable.

The Agency therefore decided that Dupixent'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 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 10-2025.