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Withdrawal of application to change the marketing authorisation for Dupixent (dupilumab)

Sanofi Winthrop Industrie withdrew its application for the use of Dupixent in the treatment of adults with moderate-to-severe bullous pemphigoid, an autoimmune skin disease causing widespread itching and blisters affecting the skin and sometimes the inside of the mouth.

The company withdrew the application on 24 June 2026.

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 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 (continuing) 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 withintense itching) in adults. It is used with or without topical (applied to the skin) corticosteroids;

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- eosinophilic oesophagitis (an allergic inflammatory condition of the food pipe) 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 and lasts for at least 6 weeks. It is used in patients aged 2 years and over in whom treatment with antihistamines does not work well enough and who have not received medicines targeting immunoglobulin E (IgE).

Dupixent has been authorised in the EU since September 2017. It contains the active substance dupilumab and is available as pre-filled pens or syringes containing dupilumab in a solution for injection under the skin.

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

What change had the company applied for?

The company applied for an extension of indication to add the treatment of bullous pemphigoid in adults. During the procedure, the company amended the indication to the treatment of moderate to severe bullous pemphigoid in adults.

How does Dupixent work?

People who have the diseases for which this medicine is used 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. In bullous pemphigoid, Dupixent was expected to work in the same way as it does in its authorised uses.

What did the company present to support its application?

The company presented the results of a main study involving 106 adults with bullous pemphigoid.

Patients received either Dupixent or placebo in addition to background treatment of oral corticosteroid medicines until patients achieved stable disease control. The main measure of effectiveness was the proportion of patients who achieved sustained remission, defined as no need for corticosteroids by week 16 of treatment and no disease relapse (when symptoms come back) and need for rescue therapy by week 36 of treatment.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

What did the Agency recommend at that time?

The main study did not achieve its main objective and the results for the other outcomes were not robust enough due to limitations with the study design.

Any improvements seen were modest, with a high level of uncertainty, and the additional supporting information, mainly from real-world experience, was not sufficient to confirm that the medicine is effective.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Dupixent in the treatment of bullous pemphigoid did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that it withdrew the application due to a divergence of views with the Agency's scientific committee, the CHMP, regarding the sufficiency of the data supporting the proposed extension of use for Dupixent.

Does this refusal affect patients in clinical trials or compassionate use programmes?

The company informed the Agency that there are no patients receiving Dupixent for the treatment of bullous pemphigoid in clinical trials or as part of a compassionate use program in the EU.

What is happening with Dupixent in other uses?

The withdrawal does not impact the authorised uses of this medicine.