



<b>Early Access to Medicines Scientific Opinion - Public Assessment Report</b>	
<b>Product</b>	<b>Dupixent (dupilumab)</b>
<b>Condition</b>	<b>Atopic dermatitis is a type of eczema that causes inflammation in the skin.</b>
<b>Full indication</b>	<b>For the purpose of EAMS, Dupixent is being made available to adolescent patients <math>\geq 12</math> to <math>&lt; 18</math> years of age with severe atopic dermatitis who have responded inadequately to at least one systemic therapy or where the available systemic therapies are not recommended or are not tolerated.</b>
<b>Company</b>	<b>Sanofi</b>
<b>EAMS number</b>	<b>04425/0001</b>

## Introduction

The aim of the Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed medicines to UK patients that have a high unmet clinical need. The MHRA scientific opinion provides benefit and risk information to doctors who may wish to prescribe the unlicensed medicine under their own responsibility. More information about the scheme can be found here:

<http://www.mhra.gov.uk/Howweregulate/Innovation/EarlyaccesstomedicinesschemeEAMS/index.htm>

The scientific opinion is based on the information supplied to the MHRA on the benefits and risks of a promising new medicine. As such this is a scientific opinion and should not be regarded as a medicine licensed by the MHRA or a future commitment by the MHRA to licence such a medicine. The General Medical Council's guidance on prescribing unlicensed medicines can be found here: <https://www.gmc-uk.org/guidance/28349.asp>

Dupixent

## What is Dupixent?

Dupixent contains a monoclonal antibody known as dupilumab. It is a biological medicine that targets a specific molecule in the body. Dupixent is given by injection and is supplied as a ready to use syringe and needle.

## What is Dupixent used to treat?

Dupixent is used to treat severe atopic eczema (also called atopic dermatitis). Dupixent is a licensed medicine that is approved for some adult patients, aged 18 years and over, with moderate to severe atopic dermatitis. Dupixent is now being made available through EAMS for adolescent patients between 12 and 17 years of age who have severe eczema that is not controlled with the available therapies.

## How is Dupixent used?

Dupixent is given by injection under the skin once every two weeks. A single syringe and needle delivers one dose. Dupixent is available in two strengths so that an appropriate dose can be administered depending on the patient's body weight. If the patient wishes and the doctor considers it

appropriate, either they or a caregiver can administer the injection, after suitable training has been provided by their doctor or nurse. It is recommended that adolescent patients are supervised by an adult when giving their injection.

Dupixent can only be prescribed by physicians experienced in the treatment of dermatological conditions.

### **How does Dupixent work?**

Dupixent contains dupilumab, an immunotherapy drug targeted to one aspect of the immune system that is involved in chronic skin inflammation of atopic dermatitis patients. Dupilumab works by attaching to a molecule called the IL-4 receptor alpha subunit which sits primarily on the surface of cells of the immune system. This interferes with messages of two molecules, IL4 and IL13 that trigger the inflammation in the skin. Eczema patients have an overactive chronic inflammatory response and dupilumab works by dampening this down.

### **How has Dupixent been studied in adolescent patients with atopic dermatitis?**

Dupixent was studied in a clinical trial that enrolled a total of 251 adolescent patients with atopic dermatitis, more than 50% of whom would be categorised as having severe eczema (atopic dermatitis) at the start of the trial. More than 40% of patients had received prior systemic therapy (drugs in the form of tablets or injections). The trial compared Dupixent with a placebo (inactive) drug. Neither the patients nor their doctors knew which treatment they had been assigned to.

### **What are the benefits and risks of Dupixent?**

#### *Benefits*

In adolescent patients, as in adults, Dupixent produces a meaningful reduction in the severity of eczema lesions as well as reducing their extent (how much of the body's surface is affected). Patients also experience a significant reduction in itching and an improvement in sleep and quality of life.

#### *Risks*

Dupixent overall has an acceptable safety profile.

During treatment with Dupixent, as with other monoclonal antibody treatments, patients may occasionally develop a serious and unpredictable allergic reaction to the drug, but this is rare. Conjunctivitis occurred more commonly in adolescent patients, as in adults, receiving Dupixent compared with placebo. The reason for this side-effect is unknown. Referral to an eye specialist is recommended if the eye inflammation does not resolve with standard treatment.

### **Why has Dupixent been given a positive Early Access to Medicine Scientific opinion?**

Severe atopic dermatitis (eczema) is a disease that has a major impact on quality of life and the treatment options available are limited and can have harmful effects. Under EAMS, Dupixent is being made available to adolescent patients with the highest need. Dupixent results in meaningful improvement in the extent and severity of eczema as well as in the symptom of itch and in some patients the improvement may be marked. The risks associated with Dupixent can be managed and do not outweigh the benefits.

### **What are the uncertainties?**

Dupixent is a targeted immunotherapy drug and as such is not considered to present the same risks as drugs that cause a general suppression of the immune system. However, the long term risks are still unknown.

Dupixent has not been studied in pregnant women or those who are breast-feeding. If a woman becomes pregnant while receiving dupilumab treatment, the treatment should be stopped.

There is insufficient information at present on the benefits and risks of Dupixent in atopic dermatitis (eczema) patients under the age of 12 years. Dupilumab is not being made available through EAMS to children less than 12 years of age for this reason.

**Are there on-going clinical studies?**

There are ongoing studies of Dupixent in the long term treatment of adolescents with atopic dermatitis, studies in children under 12 years of age with atopic dermatitis and studies in patients with other atopic conditions.

**What measures are in place to monitor and manage risks?**

A risk management plan has been developed to ensure that Dupixent is used as safely as possible. Based on this plan, the company that makes Dupixent must ensure that all healthcare professionals expected to use the medicine, as well as patients, are provided with information on the medicine including the side effects and recommendations for minimising these side effects.

Information will be collected about patients before they enter the scheme. Healthcare professionals will be asked by the company to report adverse effects experienced by patients receiving Dupixent through the scheme. These safety data will be reviewed and reported to the MHRA on a regular basis by the company.

Patients in the Early Access to Medicines Scheme will also receive an alert card from their doctor summarising the important risks with the medicine and the details of their treating dermatologist. Patients should carry the card with them at all times in case they need treatment or advice from a healthcare professional who is not familiar with Dupixent treatment.

**Other information about Dupixent – see EAMS Treatment Protocol**

Withdrawn