

Early Access to Medicines Scientific Opinion - Public Assessment Report

Dupilumab

For the purpose of EAMS, dupilumab is being made available to adult patients with severe atopic dermatitis who have failed to respond, or who are intolerant of or ineligible for all approved therapies. Dupilumab can be used with or without topical corticosteroids.

Sanofi

EAMS number 44513/0001

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 license such a medicine. The General Medical Council's guidance on prescribing unlicensed medicines can be found here: <http://www.gmc-uk.org/mobile/news/14327>

Dupilumab

What is Dupilumab?

Dupilumab is a type of medicine known as a monoclonal antibody that targets a specific molecule in the body. Dupilumab is given by injection under the skin and is supplied as a ready to use syringe and needle.

What is Dupilumab used to treat?

Dupilumab is used to treat patients with severe allergic eczema (also called atopic dermatitis) who have not responded to all the approved treatments available to them.

How is Dupilumab used?

Dupilumab is given by injection under the skin once every two weeks. A single syringe and needle delivers one dose. If the patient wishes, either they or a caregiver can administer the injection provided they have received training beforehand from their doctor or nurse.

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

How does Dupilumab work?

Dupilumab is a type of 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 Dupilumab been studied?

Dupilumab has been studied in clinical trials of more than 1500 patients with moderate to severe atopic dermatitis in which dupilumab alone or with a topical treatment was compared with a placebo (inactive) drug. Patients with severe eczema who had exhausted all available treatment options – the population for whom dupilumab is to be made available for the purpose of EAMS - were included within these trials. More than 700 atopic dermatitis patients have received dupilumab for a period of at least one year. Dupilumab has been studied as a treatment on its own and together with steroid creams.

What are the benefits and risks of Dupilumab?

Benefits

Dupilumab 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 reduction in itching and an improvement in sleep and quality of life.

Risks

Dupilumab overall has an acceptable safety profile.

During treatment with dupilumab, as with other monoclonal antibody treatments, patients may occasionally develop a serious and unpredictable allergic reaction to the drug. But this is rare. Cold sores and eye inflammation occurred more commonly in patients receiving dupilumab compared with placebo but these risks can be managed with standard treatments. There is a risk of worsening of asthma when dupilumab is stopped which may require an adjustment of medication.

Why has Dupilumab been given a positive Early Access to Medicine Scientific opinion?

Severe atopic 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, dupilumab is being made available to those patients with the highest need who have run out of treatment options. Dupilumab results in meaningful improvement in the extent and severity of eczema as well as in itch and in some patients the improvement may be marked. The risks associated with dupilumab can be managed and do not outweigh the benefits.

What are the uncertainties?

Dupilumab 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.

Dupilumab 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 dupilumab in eczema patients under the age of 18 years. Dupilumab is not being made available to children and adolescents under EAMS for this reason.

Are there on-going clinical studies?

Ongoing studies of dupilumab in the long term treatment of atopic dermatitis are being conducted in adults. There are also ongoing studies in children.

What measures are in place to monitor and manage risks?

A risk management plan has been developed to ensure that dupilumab is used as safely as possible. Based on this plan, the company that makes dupilumab 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 dupilumab 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 dupilumab treatment.

Other information about Dupilumab – see EAMS Treatment Protocol

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