

Early Access to Medicines Scheme – Treatment protocol – Information for patients

Introduction

The aim of the Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed medicines (medicines that do not have a marketing authorisation) to UK patients that have a high unmet clinical need. The medicines included in the scheme are those that are intended to treat, diagnose or prevent seriously debilitating or life threatening conditions where there are no adequate treatment options. More information about the scheme can be found here:

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

The information below is intended for you, the patient, and is provided by the pharmaceutical company that manufactures the medicine. This medicine does not yet have a drug licence (also called a marketing authorisation). More information about medicines licensing can be found here:

<http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Adviceandinformationforconsumers/MymedicineFromlaboratorytopharmacyshelf/Licensingmarketingauthorisation/index.htm>

This medicine can be prescribed for individual patients to meet specific needs provided they are given sufficient information about the medicine to make an informed decision. Informed consent should be obtained from you prior to treatment.

This information is provided to help you decide with your doctor on whether to use the medicine and helps explain how to use the medicine in accordance with the pharmaceutical company's instructions for safe and proper use. Whilst you are using this medicine, data will be collected on the use and safety profile of the medicine, to ensure that the benefits of taking the medicine outweigh any potential risks.

Information for the patient:**Dupilumab 300 mg solution for injection in a pre-filled syringe**

dupilumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What dupilumab is and what it is used for
2. What you need to know before you use dupilumab
3. How to use dupilumab
4. Possible side effects
5. How to store dupilumab
6. Contents of the pack and other information

1. What dupilumab is and what it is used for

In the Early Access to Medicines Scheme (EAMS) dupilumab is being used to treat adult patients with severe atopic dermatitis, (also known as atopic eczema), who have failed to respond, or who are intolerant of or ineligible for all approved treatments. Dupilumab can be used with or without topical corticosteroids. Dupilumab is a monoclonal antibody (a type of specialised protein) that blocks the action of proteins called IL-4 and IL-13. IL-4 and IL-13 play a major role in the symptoms of atopic dermatitis.

2. What you need to know before you use dupilumab**Do not use dupilumab**

- if you are allergic to dupilumab or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, ask your doctor for advice before using dupilumab.
- if you have a short term or long term active infection including TB/HIV/HepB/parasitic infection
- if you have a history of an immunosuppressive condition or are taking medication for an immunosuppressive condition
- if you have been taking part in a clinical trial with an investigational medicine within the previous 12 weeks
- if you are a pregnant or breast feeding women

Talk to your doctor if you think any of the above applies to you.

Warnings and precautions

Talk to your doctor or nurse before using dupilumab:

Allergic reactions

Dupilumab can potentially cause serious side effects, including generalized allergic (hypersensitivity) reactions. You must look for signs of these conditions while you are taking dupilumab.

Stop taking dupilumab and tell your doctor or seek medical help immediately if you notice any signs of an allergic reaction. Such signs are listed under “Serious side effects” in section 4.

Parasitic (intestinal parasites) infection

Dupilumab may weaken your resistance to infections caused by parasites. If you already have a parasitic infection it should be treated before you start treatment with dupilumab. If you are travelling to a region where these infections are common check with your doctor.

→ **Tell your doctor prior to discontinuing dupilumab**

Other Allergic and or Atopic Conditions (e.g. asthma)

Prior to discontinuing dupilumab check with your doctor if you need to adjust your treatment or need to manage other allergic and or atopic conditions.

→ **Check with your doctor prior to discontinuing dupilumab**

Cold sores (oral herpes virus infection)

Dupilumab is associated with an increased risk of cold sores. Cold sores, including symptoms of impending cold sores (tingling, burning e.g.) should be treated promptly. If cold sores do not improve with treatment you should see your doctor.

Children and adolescents

Dupilumab should not be used in children and adolescents below 18 years of age.

Other medicines and dupilumab

Tell your doctor or nurse:

- if you are using, have recently used or might use any other medicine.
- if you have recently had or are due to have a vaccination. You should not be given certain types of vaccines while using dupilumab.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant, or are planning to have a baby, tell your doctor before using this medicine. The effects of this medicine in pregnant women are not known. Pregnant women are therefore excluded from this EAMS.

You should use a reliable form of contraception while you are taking dupilumab.

Stop taking dupilumab and tell your doctor immediately if you become pregnant.

You should not breast feed while taking dupilumab.

Driving and using machines

Dupilumab is unlikely to influence your ability to drive and use machines.

Dupilumab contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 300 mg dose, i.e., essentially “sodium-free”.

3. How to use dupilumab

Always use this medicine exactly as your doctor has told you. Check with your doctor or nurse if you are not sure how to use this medicine.

Dupilumab is given by injection under your skin (subcutaneous injection). You and your doctor or nurse should decide if you should inject dupilumab yourself..

It is important not to try to inject yourself until you have been trained by your doctor or nurse. A caregiver may also give you your dupilumab injection after proper training.

Your doctor will give you a dosing card to tell you when your injections are due. You should complete this whenever you give yourself your injection. This will help you ensure that you are taking your medicine at the right time.

Each syringe contains one dose of dupilumab (300 mg). Each syringe delivers only one dose. The syringe should not be shaken.

Read the “Instructions for Use” for the syringe carefully before using dupilumab.

How much dupilumab is given and for how long

Your doctor will decide how much dupilumab you need and for how long.

The recommended dose is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week administered as subcutaneous injection.

If you use more dupilumab than you should

If you have received more dupilumab than you should or the dose has been given sooner than prescribed, inform your doctor.

If you forget to use dupilumab

If you have forgotten to inject a dose of dupilumab, talk to your doctor.

If you stop using dupilumab

Do not stop using dupilumab without speaking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

Follow up with your doctor

During the EAMS you will be required to see your doctor after the first month of initiating treatment, and thereafter every three months.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Dupilumab can cause serious side effects, including generalized allergic (hypersensitivity) reactions.

If you develop a generalized allergic (hypersensitivity) reaction, stop using dupilumab and talk to your doctor right away.

Other side effects

Very Common (may affect more than 1 in 10 people):

- injection site reactions

Common (may affect up to 1 in 10 people):

- eye dryness, redness and or itching
- eyelid itching, redness and or swelling
- eye infection
- cold sores (e.g. lips and skin)

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You should also record details of your side effect in your patient diary. If you experience one of the side effects listed in the front of your diary you should contact your dermatologist immediately. You should also report any side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

5. How to store dupilumab

Keep this medicine out of the sight and reach of children.

Dupilumab should be stored in a refrigerator (2°C to 8°C).

Do not use this medicine after the expiry date which is stated on the label and carton after "use by end". The date refers to the last day of that month.

Store in the original carton in order to protect from light.

Do not use this medicine if you notice that the medicine is discoloured or has particles in it.

Do not throw away any medicines via wastewater or household waste. Ask your doctor, pharmacist or nurse how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What dupilumab contains

- The active substance is dupilumab.
- Each pre-filled syringe contains 300 mg of dupilumab in 2 ml solution.
- The other ingredients are sucrose, L-arginine hydrochloride, L-histidine, polysorbate 80, sodium acetate, water for injection and acetic acid for pH adjustment.

What dupilumab looks like and contents of the pack

Dupilumab is a clear to slightly opalescent, colourless to pale yellow solution supplied in a glass pre-filled syringe.

Dupilumab is available in a pack containing 1 pre-filled syringe.

Scientific Opinion Holder

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Additional information:

Before treatment starts, all patients will have the scheme explained to them using the **Informed Consent Form**. They will be asked to sign this document and will be given a copy to keep.

In addition to the reporting of side effects, Sanofi would like to collect additional data on how patients' atopic dermatitis and general health are affected whilst taking dupilumab. This will take place before starting dupilumab, after the first month, and during every three months visit. Details regarding the collection of these data and its use by Sanofi are set out in the **Informed Consent Form**. Your data will be stored securely and anonymously and will be used for research purposes.

Additionally, patients will be given a **Patient Alert Card**. This alerts any other healthcare professional that may treat the patient that they are receiving dupilumab through an early access scheme, and provides information about their dermatologist, including out of hours contact details, and the Company's contact information.

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