Medicines & Healthcare products Regulatory Agency

MHRA

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:

Dupixent 300 mg solution for injection in pre-filled syringe
Dupixent 200 mg solution for injection in pre-filled syringe

dupilumab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 Dupixent is and what it is used for

In this Early Access to Medicines Scheme (EAMS), **Dupixent** is being made available to adolescent patients 12 to 17 years of age with severe atopic dermatitis (also known as atopic eczema) who have responded inadequately to at least one systemic therapy or where the available systemic therapies are not recommended or are not tolerated.

Dupixent contains dupilumab, which is a monoclonal antibody (a type of specialised protein) that blocks the action of proteins called interleukin-4 (IL-4) and IL-13. IL-4 and IL-13 play a major role in the symptoms of atopic dermatitis.

Dupixent may be used with eczema (atopic dermatitis) medicines that you apply to the skin or it may be used on its own.

Using Dupixent for atopic dermatitis can improve the condition of your skin and reduce itching. Dupixent has also been shown to improve symptoms of pain, anxiety and depression associated with atopic dermatitis. In addition, Dupixent helps improve sleep disturbance and overall quality of life.

2. What you need to know before you use Dupixent

Do not use Dupixent:

- 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 Dupixent.
- 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
- 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 Dupixent.

Allergic reactions

Very rarely, Dupixent can cause serious side effects, including allergic (hypersensitivity) reactions. You must look out for signs of these conditions (i.e. fever, general ill feeling, swollen lymph nodes, hives, itching, joint pain, skin rash) while you are taking Dupixent.

Stop using Dupixent and tell your doctor or get medical help immediately if you notice any signs of an allergic reaction. Such signs are listed under "Serious side effects" in section 4.

Immunosupressives

Use of Dupixent with other systemic immunosuppressives should be avoided. Your doctor may reduce your dose of immunosuppressive medication during and just before the introduction of Dupixent.

Live or attenuated vaccines

Dupixent should not be co-administered with live or attenuated vaccines. Inactivated (killed) vaccines may be given concurrently with Dupixent.

Parasitic (intestinal parasites) infection

Dupixent 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 Dupixent. Check with your doctor if you have diarrhea, gas, upset stomach, greasy stools and dehydration which could be a sign of a parasitic infection. If you are travelling to a region where these infections are common, check with your doctor.

➔ **Tell your doctor prior to discontinuing Dupixent**

Asthma

If you have asthma and are taking asthma medicines, do not change or stop your asthma medicine without talking to your doctor. Talk to your doctor before you stop Dupixent.

Eye problems

Talk to your doctor if you have any new or worsening eye problems, including eye pain or changes in vision. You may be referred to a specialist for further treatment.

Cold sores (oral herpes virus infection)

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

Children and adolescents

Dupixent should not be used in children below 12 years of age.

Other medicines and Dupixent
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.

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 Dupixent.

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

You should not breast feed while taking Dupixent.

Driving and using machines
Dupixent is unlikely to influence your ability to drive and use machines.

Dupixent contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 300 mg or 200 mg dose, i.e. is essentially "sodium-free".

3. How to use Dupixent
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.

Dupixent is given by injection under your skin (subcutaneous injection). You and your doctor or nurse should decide if you should inject Dupixent yourself. In adolescents 12 to 17 years, it is recommended that Dupixent be administered by or under supervision of an adult.

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 Dupixent 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 Dupixent (300 mg or 200 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 Dupixent is given and for how long
Your doctor will decide how much Dupixent you need and for how long.

Dupixent is given by injection under the skin (subcutaneous injection).

Recommended dose in adolescents
The recommended dose of Dupixent for adolescents (12 to 17 years of age) with atopic dermatitis is based on body weight:

Body Weight of Patient	**Initial Dose**	**Subsequent Doses (every other week)**
less than 60 kg	400 mg (two 200 mg injections)	200 mg
60 kg or more	600 mg (two 300 mg injections)	300 mg

The recommended dose (≥ 60 kg body weight) is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week administered as subcutaneous injection.

The recommended dose (< 60 kg body weight) is an initial dose of 400 mg (two 200 mg injections), followed by 200 mg given every other week administered as subcutaneous injection.

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

If you forget to use Dupixent
If you have forgotten to inject a dose of Dupixent, talk to your doctor.

If you stop using Dupixent
Do not stop using Dupixent 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.

Dupixent can cause serious side effects, including very rare allergic (hypersensitivity) reactions; the signs of allergic reaction may include:

- fever
- general ill feeling
- swollen lymph nodes
- hives
- itching
- joint pain
- skin rash

If you develop an allergic reaction, stop using Dupixent and talk to your doctor right away.
Other side effects
Very Common (may affect more than 1 in 10 people):

- injection site reactions (i.e. redness, swelling, and itching)

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

- headache
- eye dryness, redness and or itching

- eyelid itching, redness and or swelling
- eye infection
- cold sores (e.g. lips and skin)
- eosinophilia (increase in some white blood cells)

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 or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Dupixent
Keep this medicine out of the sight and reach of children.

Dupixent should be stored in a refrigerator (2°C to 8°C). If necessary, pre-filled syringes may be kept at room temperature up to 25°C for a maximum of 14 days. Do not store above 25°C. If you need to permanently remove the carton from the refrigerator, write down the date of removal in the space provided on the outer carton, and use Dupixent within 14 days.

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 cloudy, 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 Dupixent contains
- The active substance is dupilumab.
- Each pre-filled syringe contains 300 mg of dupilumab in 2 ml solution for injection or 200 mg of dupilumab in 1.14 ml solution for injection.
- The other ingredients are sucrose, L-arginine hydrochloride, L-histidine, polysorbate 80, sodium acetate, water for injection and acetic acid for pH adjustment.

What Dupixent looks like and contents of the pack
Dupixent is a clear to slightly opalescent, colourless to pale yellow solution supplied in a glass pre-filled syringe.

Dupixent is available as 300 mg pre-filled syringes in a pack containing 2 pre-filled syringe.

Dupixent is available as 200 mg pre-filled syringes in a pack containing 1 pre-filled syringe.

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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 Dupixent. This will take place before starting Dupixent, 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[2]

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