

DUPILUMAB FOR ATOPIC ECZEMA

What are the aims of this leaflet?

This leaflet has been written to help you understand more about dupilumab (Dupixent®). It tells you how it works, why you have been chosen for treatment, possible side-effects, answers to some frequently asked questions, and where you can find out more.

What is dupilumab and how does it work?

Dupilumab is a biologic medicine that has been designed to treat eczema. It works by reducing inflammation. It works on chemical messengers (known as a 'cytokines') in the body called 'interleukin-4' (IL-4) and 'interleukin-13' (IL-13).

Why have I been selected for treatment with dupilumab?

National guidelines recommend dupilumab for the treatment of moderate to severe eczema in adults who have not improved with at least one tablet medication, or when tablet medications cannot be used. The only skin condition dupilumab is recommended to treat is <u>atopic eczema</u>.

Is dupilumab safe for children and adolescents?

Dupilumab is not yet routinely available for those aged less than 18 years, but this is expected to change as some 12 to 17-year-olds are already being treated with dupilumab in the UK as part of an early access scheme, prior to full approval of the drug in this age group. It is not known whether dupilumab is safe or effective in children under 12 years of age, but research is ongoing.

Are there any alternatives to dupilumab?

Most patients will have tried at least one tablet medication before being offered dupilumab. Alternatives to starting dupilumab would be to try a different tablet medication, with options including <u>methotrexate</u>, <u>ciclosporin</u>, <u>mycophenolate mofetil</u>, and <u>azathioprine</u>. Other alternatives are frequent use of cream treatments and consideration of phototherapy, which are options that can be discussed with your dermatologist. There are no other biologic medicines approved for eczema in the UK at present (June 2019), although others may become available in the future.

How do I take dupilumab?

Dupilumab is given as an injection under your skin (subcutaneously) using a pre-filled pen device. A nurse or doctor will teach you how to use the pen to inject yourself, and details are also given in the package insert. Injections are made under the skin of the stomach, thighs or upper outer arms. You will be provided with a special bin so that you can dispose of your injections safely.

How often should I take dupilumab?

Dupilumab should be injected every 2 weeks.

What should I do If I miss a dose?

If a dose is missed, have the missed dose as soon as possible. The next dose should then be 2 weeks after this dose.

How do I store dupilumab?

Dupilumab must be stored in a refrigerator (between 2 to 8°C), and it is recommended that the syringes are kept in their carton to protect them from light. The expiry date of each syringe should be checked prior to use.

Once dupilumab has been removed from the refrigerator, it must either be used within 14 days or thrown away, and should not be put back in the fridge. Any medication that has been warmed above 25°C should not be used.

Can I travel abroad while taking dupilumab?

Please discuss with your dermatologist if you are planning to travel abroad. It is important to keep the dupilumab at the correct temperature. Depending on where you are travelling, precautions should be taken against infections.

Can I still use topical steroids?

Whilst on dupilumab, topical steroid creams and ointments can still be used for active eczema. In a trial that permitted use of creams alongside dupilumab, two in three people still needed to use topical steroids, or even tablet medications, for eczema flares despite taking dupilumab.

What are the side effects of dupilumab?

Trial evidence of more than 1500 people shows that dupilumab is a well-tolerated treatment. Very few patients stopped taking the medication due to side effects. Long-term safety data beyond one year is still being collected.

Up to 1 in 5 people taking dupilumab develop conjunctivitis, which can cause itching, redness and dryness of the eye. This is usually mild and usually treated without needing to stop dupilumab.

Other common side-effects (may affect up to 1 in 10 people) are headache, eczema around the eyes, a sore throat, cold sores/ herpes in the mouth, and a mild reaction at the injection site (redness, swelling, itching, and bruising).

If a more severe allergic reaction occurs (which is very rare), with features such as a swollen face/tongue, difficulty breathing, feeling lightheaded, itching all over, widespread rash, fever, and joint pain, you should dial 999 or immediately go to a hospital Accident and Emergency department. Afterwards you should make sure that your dermatologist and GP have been informed and you should stop using dupilumab.

How is conjunctivitis (red eyes) treated?

You should inform your dermatologist if you develop red eyes as this may be due to conjunctivitis. For people with severe conjunctivitis which reduces vision or is interfering with everyday activities, you may be referred to an ophthalmologist (eye specialist). For mild cases, treatments include lubricating eye drops.

What happens before starting treatment?

Before you start taking dupilumab, you will have a consultation with your dermatologist/team including a clinical examination. You will be asked about any current or past infections (such as human immunodeficiency virus (HIV) infection, viral hepatitis, and parasitic infections) and blood tests for some of these will be performed before starting. It is also important to tell your dermatologist if: you are pregnant or plan to become pregnant, are breastfeeding or plan to breastfeed, and/or have had previous eye problems such as eye infections. Your dermatologist will discuss your individual situation with you and explain more about this.

Can I have vaccines whilst taking dupilumab?

Patients on dupilumab should not be given any live vaccines, such as those for polio, rubella (German measles), and yellow fever. 'Inactivated' or 'non-live' vaccinations can be used. You should always check with your healthcare professional when having a vaccination and make them aware that you are on dupilumab. Further advice is available on the BAD website with a patient information leaflet on <u>immunisation</u>.

I have an allergy. Can I take dupilumab?

You should discuss this with your dermatologist. Other products contained in the dupilumab injection include L-arginine hydrochloride, L-histidine, polysorbate 80, sodium acetate, acetic acid, sucrose, and water.

Does dupilumab affect pregnancy and breastfeeding?

The effects of dupilumab in pregnant women are not known. It is also not known whether dupilumab passes into breast milk. As dupilumab remains in the body after a dose is given, it is important to have a discussion with your doctor about using dupilumab if you are considering pregnancy and/or breastfeeding.

What will happen if I need an operation or dental surgery?

As dupilumab reduces inflammation, it may reduce your ability to fight infection. For planned procedures, you may be advised to stop dupilumab prior to the surgery. Please discuss this with your doctor or dentist.

Can I drink alcohol while taking dupilumab?

There is no known interaction between alcohol and dupilumab. UK guidelines recommend no more than 14 units of alcohol per week for both men and women.

Can I take other medicines at the same time as dupilumab?

Most medicines are safe to take with dupilumab. However, it is important that your GP and other doctors are aware that you are taking it.

Where can I get more information about dupilumab?

This information sheet does not list all of the side effects of dupilumab. If you wish to find out more about dupilumab please speak to your doctor, specialist nurse or pharmacist. For further details, look at the drug information sheet which comes as an insert with your dupilumab.

For details of source materials used please contact the Clinical Standards Unit (clinicalstandards@bad.org.uk).

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.

This leaflet has been assessed for readability by the British Association of Dermatologists' Patient Information Lay Review Panel

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