

Dupilumab factsheet

Dupilumab, also known as Dupixent[®], is a new treatment for severe eczema. Dupilumab is a 'biologic' drug and works in a different way to the other drugs that are currently available for eczema. Biologic drugs are produced by genetically-modified organisms such as bacteria or cells cultured in a laboratory. These types of drug have been used to treat severe psoriasis, asthma and arthritis for several years. They are taken in different ways – subcutaneously (under the skin), intravenously (in the vein) and sometimes orally. Dupilumab is the first biologic treatment for atopic eczema and is taken subcutaneously. There are other biologic treatments for atopic eczema that are currently undergoing research.

How does it work?

The human body uses chemical messengers called interleukins (ILs). ILs allow the different parts of our immune system to communicate and help fight off harmful viruses and bacteria. The immune system of people with inflammatory conditions like atopic eczema overreacts to allergens (e.g. dust, mould, pollen). This triggers the production of certain ILs, which cause greater inflammation. It is this chronic inflammation that leads to symptoms of eczema such as red, itchy, dry patches on the skin.

Biologics work by blocking ILs from binding to their cell receptors (protein molecules that receive chemical signals from outside a cell); this stops the immune system from overreacting. Dupilumab works on two specific ILs thought to contribute to atopic conditions: IL-4 and IL-13. By blocking IL-4 and IL-13 from binding to their cell receptors, dupilumab limits the overreaction of the immune system, dampening down the chronic inflammatory response and lessening the symptoms of atopic eczema.

If you think of a chemical messenger such as IL-4 as a key, and a cell receptor as a lock, a biologic drug works in a similar way to fixing a coin over the keyhole so that the key (IL-4) is unable to get into the lock (the cell receptor).

Immunosuppressive drugs for eczema (e.g. azathioprine, ciclosporin, methotrexate and mycophenolate mofetil) suppress many different chemical messengers that control inflammation, whereas biologic drugs suppress just one or two of these chemical messengers. Drugs that only block one or two chemical messengers have fewer potential side effects than conventional immunosuppressive drugs.

What has the research shown?

Clinical trials of dupilumab have shown that it produces a meaningful reduction in the severity of eczema, as well as a reduction in the body surface affected by eczema in the majority of patients receiving it. Many patients receiving dupilumab also experienced a reduction in itching and an improvement in sleep and quality of life. The trial data results showed that many patients taking dupilumab no longer needed to apply as much topical steroid while taking the drug.

Is it available on the NHS?

Dupilumab received regulatory approval in September 2017 from the European Medicines Agency (EMA). It then underwent assessment by the National Institute for Health and Care Excellence (NICE), and was approved by NICE for routine use on the NHS in England and Wales in August 2018. The healthcare system in Northern Ireland

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usually also implements NICE guidance. The Scottish Medicines Consortium (SMC) accepted dupilumab for use by NHS Scotland in September 2018.

Who is it for?

Dupilumab is licensed for the treatment of adults and children aged 12-17 with moderate-to-severe atopic dermatitis (atopic eczema) who are possible candidates for systemic therapy. It is unlikely that anyone whose eczema is not at the severe end of the spectrum will be considered for dupilumab. To be eligible for dupilumab you will need to have tried at least one immunosuppressive drug (e.g. azathioprine, ciclosporin, methotrexate or mycophenolate mofetil) and the drug needs to have not worked effectively for you. You may also be eligible for dupilumab if you have been found to be ineligible for immunosuppressive drugs, for example, if it is known that your body will not tolerate them. Dupilumab is significantly more expensive than other drugs currently available for eczema, which might make it more difficult to access.

How do I go about getting it?

If you think you might be eligible for dupilumab, speak to your dermatologist about the possibility of trying it. It will not be offered by your GP; you will need to be referred to see a specialist dermatologist in a hospital.

How is it administered?

Dupilumab is given by injection under the skin once every two weeks. A single syringe and needle delivers one dose. Unlike other drug treatments for eczema, patients are able to administer dupilumab themselves after having received appropriate training from a healthcare professional. Patients self-administering the injection are advised to inject into their thigh or abdomen (except for the 5cm around the navel). If a healthcare professional is administering the injection, the drug can be injected into the upper arm. The injection site needs to be rotated and patients must avoid injecting into skin that is tender, damaged or scarred. Dupilumab must be stored in the

fridge (2-8°C). If necessary, the pre-filled syringes may be kept at room temperature (maximum 25°C) for a maximum of 14 days. They cannot be refrigerated again once they have reached room temperature.

How long do you take it for?

Dupilumab is an ongoing treatment rather than a treatment that is used for a fixed amount of time. Patients are reviewed after 16 weeks to see how effectively the treatment is working for them. If a patient's eczema has not responded adequately to dupilumab after 16 weeks, the treatment may be stopped. Patients would be expected to show a significant reduction in eczema symptoms and an improvement in quality of life after having taken dupilumab for 16 weeks.

Can people taking dupilumab still use topical steroids and emollients?

Yes, patients taking dupilumab will be expected to use topical steroids and emollients to manage their eczema alongside dupilumab.

Could I take it while breastfeeding or pregnant?

It is best to avoid taking dupilumab while breastfeeding. As this is a new treatment, there is currently only limited research data on the use of dupilumab by pregnant women. Dupilumab should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is important to speak to your dermatologist about your specific situation.

What are the risks of dupilumab?

Common side effects of dupilumab include eye inflammation (especially conjunctivitis), headaches and cold sores. People who have asthma as well as eczema could experience a worsening of their asthma symptoms if they stop taking dupilumab. Very rare side effects include serum sickness-like reactions: fever, rash and joint pain and/or swelling. The safety profile of dupilumab is superior to that of immunosuppressive drugs.

Can children take dupilumab too?

In August 2019 the EMA approved dupilumab for the treatment of 12-17-year-olds with moderate-to-severe atopic eczema. This meant that children in England who were eligible for dupilumab could start treatment at designated NHS centres in England. For Scotland, Wales and Northern Ireland, decisions are expected at the end of 2019 or the beginning of 2020. Before the EMA made this decision, dupilumab was available for 12-17-year-olds under the Early Access to Medicines Scheme (EAMS), prior to regulatory approvals being granted. The EAMS for dupilumab has now closed, and anyone who started their dupilumab treatment under the EAMS process will continue as before. To be eligible for dupilumab, children need to be candidates for systemic therapy.

Further information:

NICE: Dupilumab for treating moderate-to-severe atopic dermatitis: www.nice.org.uk/guidance/TA534
www.bnf.nice.org.uk/drug/dupilumab.html

SMC: dupilumab (Dupixent):

www.scottishmedicines.org.uk/medicines-advice/dupilumab-dupixent-fullsubmission-smc2011/

EMC: Dupixent 300 mg solution for injection in pre-filled syringe:

www.medicines.org.uk/emc/product/8553/smpc

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