Tralokinumab factsheet

Tralokinumab, also known as Adtralza®, is a treatment for moderate to severe atopic eczema (also known as atopic dermatitis) in adults and children aged 12 years and older. Tralokinumab is a type of biologic drug called a monoclonal antibody. Monoclonal antibodies are designed to target specific proteins or receptors in the body, to regulate the immune response or interfere with disease processes. They are produced in the laboratory by cloning immune cells to create identical copies of a particular antibody.

Tralokinumab comes as a solution (liquid) and is injected subcutaneously (just below the skin) with a pre-filled syringe. Tralokinumab limits the overreaction of the immune system, dampening down inflammation (red or darker areas of active eczema) and reducing itch.

How does it work?

Tralokinumab works by targeting and blocking a specific protein in the immune system called interleukin-13 (IL-13). IL-13 is a small protein involved in cell signalling and immune responses. It plays a significant role in atopic eczema. IL-13 causes inflammation and can disrupt the skin barrier and reduce proteins and lipids, causing trans-epidermal water loss and entry of irritants and allergens to the skin. The immune system of people with inflammatory conditions like atopic eczema overreacts to certain triggers and allergens (for example, dust, mould and pollen), and produces too much IL-13.

Tralokinumab works by blocking IL-13 from binding to its cell surface receptors (protein molecules that receive chemical signals from outside a cell). If you think of IL-13 as a key and a cell receptor as a lock, tralokinumab works in a similar way to fixing a coin over the keyhole so that the key (IL-13) is unable to get into the lock (the cell receptor).

By blocking IL-13 from binding to its cell receptors, tralokinumab interrupts the signalling pathways that promote inflammation and contribute to other symptoms of atopic eczema. Tralokinumab also helps restore the production and function of proteins crucial for maintaining a healthy skin barrier.

Immunosuppressive drugs for eczema (azathioprine, ciclosporin, methotrexate and mycophenolate mofetil) have broader mechanisms of action than biologic drugs. Drugs that have narrower, more targeted, mechanisms of action, like tralokinumab, have fewer potential side effects than conventional immunosuppressive drugs.

What has the research shown?

Clinical trials of tralokinumab have shown that it can quickly improve eczema severity and itch. In the clinical trials ECZTRA 1 and ECZTRA 2, at week 16, more patients receiving tralokinumab had an improvement in their atopic eczema compared with patients receiving placebo. Patients experienced meaningful improvements in itch, sleep and quality of life as early as 1-2 weeks after starting tralokinumab. The majority of patients who had benefited from tralokinumab at 16 weeks maintained skin improvement after another 36 weeks of treatment.

Is it available on the NHS?

Yes. Tralokinumab was approved for routine use in England, Wales, Scotland and Northern Ireland in 2022. Initially approved for treating eligible adults with moderate to severe atopic eczema, tralokinumab is now also available on NHS prescription to treat children aged 12 years and over. Only a dermatologist can start you on

this treatment, so you would need to be referred to a dermatologist if you're not already under the care of one.

Who is it for?

Tralokinumab is licensed for the treatment of adults and children aged 12 years and over with moderate to severe atopic eczema who are possible candidates for systemic medication (these are medications that affect the whole body, rather than being localised to a specific area or organ). The more severe the eczema, the more likely you are to be considered for a newer therapy such as tralokinumab. To be eligible for tralokinumab, you will usually need to have tried at least one systemic immunosuppressive medication (azathioprine, ciclosporin, methotrexate or mycophenolate mofetil) and this needs to have not worked effectively for you. You may also be eligible for tralokinumab if you are unable to tolerate the immunosuppressive medications listed above, or if they are not suitable for you.

How do I go about getting it?

If you think you might be eligible for tralokinumab, speak to your dermatologist about the possibility of trying it. If you're not currently under the care of a dermatologist, ask your GP for a dermatology referral. You will need to see a specialist dermatologist in a hospital to access this treatment.

How is it taken?

Tralokinumab is given by injection under the skin. The recommended dose of tralokinumab for both adults and children aged 12 years and older is an initial 600 mg dose (given as four 150 mg injections) followed by 300 mg (given as two 150 mg injections) every two weeks. Depending on how well tralokinumab works for you, your doctor may decide that you can have a dose every four weeks. For the initial dose, the four injections can be given one after another into different injection sites in the same body area.

Patients or caregivers can administer tralokinumab themselves at home after having received appropriate training from a healthcare professional. Patients or caregivers are advised to inject into the thigh or abdomen (except for the 5cm around the navel). If a healthcare professional or caregiver is administering the injection, rather than the patient themselves, the upper arm can be used as an alternative injection site. The injection site needs to be rotated with each dose, and patients must avoid injecting into tender, damaged or scarred skin.

The syringe is pre-filled and should not be shaken. Tralokinumab must be stored in the fridge (2-8°C). Wait for 30 minutes after removing tralokinumab from the fridge before injecting it, so it's at room temperature when you inject it. If necessary, the pre-filled syringes may be kept at room temperature (maximum 25°C) for up to 14 days. They cannot be refrigerated again once they have reached room temperature.

If you miss a dose at the right time, inject tralokinumab as soon as possible afterwards. Then inject the next dose at the regular scheduled time.

If you take too much or the dose has been given too early, talk to your doctor or nurse.

How long do you take it for?

Tralokinumab is an ongoing treatment rather than a treatment that is used for a fixed amount of time. Patients are reviewed after 16 weeks of starting treatment to see how effectively tralokinumab is working for them. If a patient's eczema has not responded adequately to tralokinumab after 16 weeks, the treatment may be stopped.

Can people taking tralokinumab still use emollients and topical steroids?

Yes, patients taking tralokinumab will be expected to use emollients and topical steroids to manage their eczema alongside tralokinumab. A clinical trial (ECZTRA 3) has shown that using topical steroids alongside tralokinumab provides progressive and ongoing improvement of atopic eczema.

Can I take it while pregnant or breastfeeding?

Due to limited research data, tralokinumab is not recommended if you're pregnant or breastfeeding. It's important to speak to your dermatologist about your specific situation. Tralokinumab has no effect on male or female fertility.

What are the risks of tralokinumab?

Common side effects of tralokinumab include conjunctivitis (inflammation of the eye or eyelid, also known as red or pink eye) and allergic conjunctivitis. Patients taking tralokinumab who develop conjunctivitis that doesn't resolve after standard treatment should be examined by an ophthalmologist.

Other common side effects of tralokinumab include upper respiratory tract infections (mainly reported as the common cold), injection site reactions and an increase in the number of eosinophils (a type of white blood cell) in the blood.

Since tralokinumab may reduce your resistance to infections caused by parasites, any parasite infection should be treated before starting the medication. This is important if you are travelling.

The frequency of these side effects is similar in adults and children aged 12 years and older.

Let your doctor or nurse know if you experience any side effects. Don't try to treat eye-related symptoms yourself. Seek urgent medical advice if you experience signs of an allergic reaction (such as breathing problems, swelling of the face, mouth or tongue, fainting, dizziness, feeling lightheaded, hives) or eye pain or changes in vision.

Can I have vaccinations while on tralokinumab?

It's best to discuss vaccination, including any vaccines you may need if you're planning to travel abroad, with your dermatology team. If possible, have any vaccines you may need for travelling abroad, or that you're due to have, before starting tralokinumab.

It's recommended that people on tralokinumab avoid live vaccines. These include measles, mumps and rubella (MMR), tuberculosis (BCG), yellow fever and shingles. Patients taking tralokinumab can have inactivated or non-live vaccines.

Further information

Electronic Medicines Compendium: Adtralza®

https://www.medicines.org.uk/emc/product/12725/smpc

Factsheet last reviewed July 2023.

National Eczema Society is the UK charity for everyone affected by eczema. We help support people with eczema, providing information and advice, which we deliver through our website, social media, campaigns, publications and nurse-supported Helpline. We also provide a voice for people with eczema, raising awareness of the condition, supporting research into new treatments and campaigning for better medical care.

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