PATIENT INFORMATION LEAFLET

TRALOKINUMAB

WHAT ARE THE AIMS OF THIS LEAFLET?

This leaflet has been written to help you understand more about tralokinumab. It explains how it works, why you have been chosen for treatment and possible side effects. It gives answers to some frequently asked questions and tells you where you can find more information.

WHAT IS TRALOKINUMAB AND HOW DOES IT WORK?

Tralokinumab is designed to treat atopic eczema (also known as atopic dermatitis).

Tralokinumab is a biologic medicine. Biologic medicines are made using living cells and act on the immune system. There are numerous proteins in the body and immune system called 'cytokines' which affect inflammation. Tralokinumab blocks a cytokine called 'interleukin-13' (IL-13). By doing this, tralokinumab controls the inflammation in the body and eases the symptoms of atopic eczema.

WHY HAVE I BEEN SELECTED FOR TREATMENT WITH TRALOKINUMAB?

Tralokinumab is licensed for the treatment of people of 12 years and above who have moderate to severe atopic eczema. You might be offered tralokinumab if your atopic eczema has not improved with at least one tablet medication (for example, ciclosporin, methotrexate, azathioprine or mycophenolate), or when these cannot be used.

ARE THERE ANY ALTERNATIVES TO TRALOKINUMAB?

Most patients will have tried at least one of the tablet medications listed above before being offered tralokinumab. For adult patients there are other treatment options such as baricitinib, abrocitinib and upadacitinib. For children 12 years and over abrocitinib and upadacitinib may be suitable alternatives.

WILL TRALOKINUMAB CURE MY SKIN CONDITION?

Treatments for atopic eczema usually reduce symptoms and keep the condition under control, but do not cure it.

Changes in symptoms may be seen within 2 weeks. Studies show that after 16 weeks of tralokinumab, 80% of people had seen some effect.

HOW IS TRALOKINUMAB GIVEN?

Tralokinumab Tralokinumab is given as an injection into the fat under your skin (subcutaneously) using the pre-filled syringe or pen.

Injections can be given under the skin of the stomach or thighs. A healthcare professional will teach you how to use the injection correctly. Details are also given in the package insert.

If somebody else is giving you the injection, then it can be given in the upper outer arms. You will be provided with a special bin to dispose of your injections safely.

You should wait 30 minutes after removing the syringe from the fridge for it reach toom temperature. If you are administering the pre-filled pen, then you need to allow 45-minutes to reach to room temperature.

HOW OFTEN SHOULD I HAVE TRALOKINUMAB?

Tralokinumab is available in 2 forms:

- A pre-filled syringe containing 150 mg of the medication AND
- A pre-filled pen containing 300 mg of the medication

The first dose is 600 mg which can be given in two ways:

- Four 150 mg injections with pre-filled syringes OR
- Two 300 mg injections with pre-filled pens

After the first dose, you will need a 300 mg dose every two weeks which can be given in two ways

- Two 150 mg injections with pre-filled syringes OR
- One 300 mg injection with a pre-filled pen

If your skin is much better after 16 weeks, your healthcare professional might decide you can have a 300 mg injection every 4 weeks instead of every 2 weeks.

WHAT SHOULD I DO IF I MISS A DOSE?

If a dose is missed, the missed dose should be given as soon as possible, and you should contact your dermatology team about what to do next.

HOW DO I STORE TRALOKINUMAB?

Tralokinumab must be stored in a fridge (between 2 to 8°C) in their original carton to protect them from light. The expiry date of each syringe should be checked prior to use.

Once tralokinumab has been removed from the fridge, it should not be put back. It must either be used within 14 days or disposed of in the sharps bin provided. Information about sharps bin disposal can be found on your local council's website. Medication that has been warmed above 25°C should not be used.

CAN I TRAVEL ABROAD WHILE TAKING TRALOKINUMAB?

Please discuss with your dermatologist if you are planning to travel abroad. It is important to keep the tralokinumab at the correct temperature.

Depending on where you are travelling, you may also need to take precautions against infections with parasitic worms, as tralokinumab might affect your body's immune response to this kind of infection.

CAN I STILL USE TOPICAL STEROIDS?

Yes, prescribed topical steroid creams and ointments can still be used while taking tralokinumab. For many patients topical steroid use will become less frequent over time and may just be needed for an occasional flare of eczema.

WHAT ARE THE COMMON SIDE EFFECTS OF TRALOKINUMAB?

Very common side-effects (affecting more than 1 in 10 people) are upper respiratory tract infections (sore throat, runny nose, mild cough).

Common side-effects (affecting up to 1 in 10 people) include a mild reaction around the injection area (redness, swelling, itching and pain).

Patients can also commonly (affecting up to 1 in 10 people) develop eye-related side effects. These are usually in the form of mild conjunctivitis (redness, itching) which is treated without needing to stop tralokinumab. There can be other uncommon eye side effects for which you may be referred to an ophthalmologist (eye specialist). Talk to your doctor or another healthcare professional promptly if you have any new or worsening eye problems. These can include eye watering, itching, redness, swelling, eye dryness, a feeling of gritty eyes, or a sensation of a foreign body in the eye. Seek emergency medical advice if you experience significant eye pain, or changes in your vision. .

WHAT ARE THE RARE SIDE EFFECTS OF TRALOKINUMAB?

Severe allergic reactions are very rare. If you develop 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 & Emergency department. Afterwards, you should make sure that your

dermatologist and GP have been informed of the reaction and you should stop using tralokinumab.

WHAT HAPPENS BEFORE STARTING TREATMENT?

Before you start taking tralokinumab, you will have a consultation with your dermatologist/dermatology team including a clinical examination. It is important to tell your dermatologist if you:

- Have any current or past parasitic worm infections
- Have any previous eye problems such as eye infections
- Have any allergies (see below)
- Are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed (see below)
- Are due to receive any vaccinations (see below)

Your dermatologist will discuss your individual situation with you and explain more about how these factors may affect your treatment.

I HAVE ALLERGY. CAN I TAKE TRALOKINUMAB?

People with allergies should notify their dermatology team or pharmacist before using tralokinumab.

DOES TRALOKINUMAB AFFECT PREGNANCY AND BREASTFEEDING?

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

CAN I HAVE IMMUNISATIONS (VACCINATIONS) WHILST ON TRALOKINUMAB?

Patients using tralokinumab should not be given any live or live attenuated vaccines, such as those for chickenpox/shingles, rubella (German measles), yellow fever and some polio vaccines. It is recommended that patients should be brought up to date with such vaccinations before treatment. 'Inactivated' or 'non-live' vaccines can be used. You should always make sure healthcare professionals are aware that you are taking tralokinumab when receiving a vaccination. Further advice is available on the BAD website with a patient information leaflet on immunisations).

WHAT WILL HAPPEN IF I NEED AN OPERATION OR DENTAL SURGERY?

There is no data to suggest that tralokinumab should be stopped before surgical or dental procedures. Stopping tralokinumab increases the risk of skin flare-ups. Please discuss this with your doctor or dentist.

CAN I DRINK ALCOHOL WHILE TAKING TRALOKINUMAB?

There is no known interaction between alcohol and tralokinumab. UK guidelines recommend all people drink no more than 14 units of alcohol per week.

CAN I TAKE OTHER MEDICINES AT THE SAME TIME AS TRALOKINUMAB?

Most prescribed medicines are safe to take with tralokinumab. However, it is important that your GP and other healthcare professionals involved in your care are aware that you are taking it.

WHERE CAN I GET MORE INFORMATION ABOUT TRALOKINUMAB?

This information sheet does not list all the side effects of tralokinumab. If you wish to find out more about tralokinumab, 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 tralokinumab.

Weblinks to other relevant sources:

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

NICE guidance:
https://www.nice.org.uk/guidance/ta814

Jargon Buster
https://www.skinhealthinfo.org.uk/support-resources/jargon-buster/

It is important to report suspected side effects of medicines. The Medicines and Healthcare products Regulatory Agency (MHRA) manages the Yellow Card scheme. This scheme collects information and safety concerns about medicines and medical devices. Anyone can report these side effects or concerns by using:

- the Yellow Card website www.mhra.gov.uk/yellowcard or
- the Yellow Card app

Please note that the British Association of Dermatologists (BAD) provides web links to additional resources to help people access a range of information about their treatment or skin condition. The views expressed in these external resources may not be shared by the BAD or its members. The BAD has no control of and does not endorse the content of external links.

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

BRITISH ASSOCIATION OF DERMATOLOGISTS

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