TILDRAKIZUMAB

What are the aims of this leaflet?

This leaflet has been written to help you understand more about tildrakizumab (Ilumetri®). It explains what it is, how it works, how it is used to treat skin conditions, and where more information can be found about it.

What is tildrakizumab and how does it work?

Tildrakizumab is a biologic medicine that has been designed to treat psoriasis. It works by specifically targeting a chemical messenger (known as a 'cytokine') in the body called 'interleukin-23' (IL-23). We know that IL-23 is one of the main causes of inflammation in psoriasis, and by blocking it tildrakizumab can improve symptoms of psoriasis.

What skin conditions are treated with tildrakizumab?

Tildrakizumab is used to treat psoriasis.

Why have I been selected for treatment with tildrakizumab?

You have psoriasis which is severe enough to require treatment based on national guidelines. These include failure to improve on other treatments such as methotrexate. Alternatively, there may be safety reasons why you cannot receive these standard treatments, or they may have been tried but caused you problems so you had to stop them.

How long will I need to take tildrakizumab before it has an effect?

Some improvement in your psoriasis may occur in the first few weeks of treatment, but it can take 7 months to see the full benefit. In clinical trials, more than 8 out of 10 patients were clear or nearly clear of their psoriasis by 7 months. If no significant improvement occurs the treatment will be stopped.

How do I take tildrakizumab?

Tildrakizumab is given as an injection under your skin (subcutaneously) using a pre-filled syringe device. A nurse or doctor will teach you how to use the syringe to inject yourself, and details are also provided 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 syringes safely.

Tildrakizumab must be stored in a refrigerator (between 2 to 8°C). When travelling with this treatment, you should have a cool box or cool bag with icepacks to maintain the recommended temperature. Once tildrakizumab has been removed from the refrigerator and has reached room temperature (up to 25°C) it must be used within 30 days or the expiry date on the container, whichever occurs first – it should not be put back in the fridge.

How often should tildrakizumab be taken?
You will need to give yourself one injection (100mg) of tildrakizumab for the first dose, and then inject the second dose ***4 weeks later.*** After this you should inject ***once every 12 weeks***. If you respond this can be continued to maintain long-term control of your psoriasis.

In some cases your dermatologist may recommend a higher dose of tildrakizumab which will involve injecting two syringes (200mg) for each dose. Your dermatologist will advise the most suitable dose for you.

What are the possible side effects of tildrakizumab?
Most of the side effects reported during clinical trials of tildrakizumab were mild, easily manageable, and did not require treatment to be stopped.

Mild

- *Reactions at the injection sites* are usually mild and include redness, a rash, swelling, itching, or bruising. They usually go away within 3 to 5 days. If you have pain, redness or swelling around the injection site that doesn't go away, or gets worse, contact your dermatologist.
- *Cold & flu symptoms, sore throat.*
- *Stomach flu (gastroenteritis), nausea, diarrhoea.*
- Headache.
- Back pain.

Potentially severe
Serious infections. Tildrakizumab may decrease your ability to fight infection. Your doctor will ask you about any current or past infections (particularly tuberculosis), or if you are prone to infections such as cold sores or urinary tract infections. If you develop any symptoms of tuberculosis (e.g. a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor. Your doctor will also ask if you have or have ever had any disease that affects your immune system, such as cancer, human immunodeficiency virus (HIV) infection or viral hepatitis. It is advisable to avoid close contact with anyone

who has a bad cold, influenza or chest infections and wash your hands frequently during the course of this treatment.

Allergic reactions. It is a possible that some patients could experience an allergic reaction to tildrakizumab. Severe reactions requiring emergency treatment are very rare.

How can the risk of side effects be minimised?

Before you start taking tildrakizumab, you will have a thorough consultation with your dermatologist/team including a clinical examination and a number of blood tests will be carried out. Additional investigations may be required depending on your medical history (for example, a chest Xray or other imaging).

Your dermatologist will go through the checklist below. These situations do not necessarily mean that treatment with tildrakizumab cannot be given, but may mean that other precautions are needed for you to have this treatment safely. Your dermatologist would discuss your individual situation and explain more about this.

- *Tuberculosis,* or close contact with someone who has had it.
- *Hepatitis or an HIV infection*, or if you think you are at risk of having these.
- *Infection and vaccination history.* If you are scheduled to have *any type of vaccination.*
- If you are scheduled to have *major surgery*.
- If you are *pregnant* or *breastfeeding* or are *planning a family*.

You are encouraged to take part in any *National Health screening programmes* at the recommended times (e.g. cervical smears and mammograms).

During tildrakizumab treatment you will be asked about side effects and have blood tests from time to time (for example every 6 months). It is advisable to keep the dermatology team and GP informed at all times of changes to your medications, planned procedures and surgery or health problems including:

- *If you get an infection, or any symptom or sign of an infection that doesn't go away,* including fever, lethargy, cough, influenza-like symptoms, burning when passing urine, dental problems, night sweats. Your dermatologist may suggest stopping tildrakizumab temporarily.

- *If you bruise or bleed very easily,* or look very pale

- *If you develop signs of a severe allergic reaction, such as a swollen face/tongue, throat tightness or difficulty with breathing (known as anaphylaxis),* **dial 999 for an ambulance immediately** and go to a hospital Accident and Emergency department. Afterwards ensure the dermatologist has been informed.

What will happen if I need an operation or dental surgery?
Tildrakizumab comes under the category of an 'immune suppressant' and therefore may increase your risk of getting an infection after a surgical procedure. For planned procedures, you may be advised to stop taking tildrakizumab prior to the surgery. Please discuss this with your doctor or dentist.

Can I have immunisations (vaccinations) whilst on tildrakizumab?

Patients on tildrakizumab should not be given any of the 'live' vaccines such as the *flu vaccine administered through the nose* (because when given this way a live vaccine is used), measles, mumps and rubella (MMR), yellow fever, bacillus Calmette-Guẻrin bacillus (BCG), rotavirus, oral typhoid, varicella (chickenpox) and herpes zoster (shingles). If you require immunisation with a live vaccine, tildrakizumab should be stopped for at least 17 weeks before (12 months in the case of shingles vaccine) and until 4 weeks after the vaccination. You should discuss this with your dermatologist.

'Inactivated" (not live) vaccines (e.g. Pneumovax and the *annual flu vaccine administered by injection*) are safe and recommended.

However, it is important to always check with the healthcare professional when having a vaccination and make them aware that you are on tildrakizumab.

For more detailed information see the British Association of Dermatologists patient information leaflet on Immunisations).

Does tildrakizumab affect pregnancy?
We do not know the effect tildrakizumab has on conception (getting pregnant), on the developing baby or on breastfed babies, and so pregnancy and breastfeeding should be avoided during tildrakizumab treatment. The effect of tildrakizumab continues for some time after stopping the treatment, so it is important that this is taken into account. If you are pregnant or are planning to

become pregnant, please discuss this with your dermatologist as they will be able to advise on your individual circumstances.

Travelling abroad while taking tildrakizumab
If travel abroad is planned, please discuss this with the dermatologist. Depending on where you are travelling, precautions may need to be taken against infections.

May I drink alcohol while taking tildrakizumab?
There is no known interaction between alcohol and tildrakizumab.

Can I take other medicines at the same time as tildrakizumab?
Most medicines are safe to take with tildrakizumab. However, it is important that your GP and other doctors are aware that you are taking it.

The BAD Biologic Interventions Register (BADBIR)
Because tildrakizumab treatment for psoriasis is relatively new, you may be asked to take part in a national register if it is prescribed for you. This register will collect valuable information on side effects and benefits and will inform doctors on how best to use tildrakizumab and similar drugs. No information will be recorded on the register without your informed consent.

Where can I get more information about tildrakizumab?
This information sheet does not list all of the side effects of tildrakizumab. If you wish to find out more about tildrakizumab 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 prescription for tildrakizumab.

Or visit the emc website to view the patient information leaflet online
https://www.medicines.org.uk/emc/product/9819/pil

Or visit the website https://www.ilumya.com/

The Psoriasis Association
https://www.psoriasis-association.org.uk/

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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