IXEKIZUMAB

What are the aims of this leaflet?
This leaflet has been written to help you understand more about ixekizumab (Taltz®). It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

What is ixekizumab and how does it work?
Ixekizumab 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-17A' (IL-17A). We know that IL-17A is one of the main causes of inflammation in psoriasis and psoriatic arthritis, and by blocking it ixekizumab can improve symptoms of these conditions.

What skin conditions are treated with ixekizumab?
Ixekizumab is used to treat psoriasis and psoriatic arthritis.

Why have I been selected for treatment with ixekizumab?
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 ixekizumab before it has an effect?
Some improvement in your psoriasis may occur in the first few weeks of treatment but it can take 3 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 3 months. If no significant improvement occurs the treatment will be stopped.

How do I take ixekizumab?
Ixekizumab is given as an injection under your skin (subcutaneously) using either a pre-filled syringe or pen device. A nurse or doctor will teach you how to use the syringe or 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.

Ixekizumab must be stored in a refrigerator (between 2 to 8°C). Ixekizumab may be stored unrefrigerated for up to 5 days at a temperature not above 30°C.

How should I take my medicine?

An ixekizumab syringe or pen holds 80 mg. ***For the first dose you will need to inject 160 mg (two injections)*** of ixekizumab. After this you will need to inject ***80 mg (one injection) every other week for six doses*** (e.g. week 2, 4, 6, 8, 10 and 12). After the first 12 weeks of treatment, you will then need to inject ***80 mg (one injection) every four weeks***. If you respond this can be continued to maintain long-term control of your psoriasis.

What are the possible side effects of ixekizumab?

Most of the side effects reported during clinical trials of ixekizumab were mild, easily manageable, and did not require discontinuation of the treatment.

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, stuffy nose (*nasopharyngitis*)*

*Stomach flu (*gastroenteritis*), diarrhoea, nausea*

*Cold sores (*Herpes simplex infections*)*

*Bacterial skin infections (*cellulitis*)*

Mild fungal infections such as athlete's foot, oral thrush (candidiasis)

*Headaches, rash, hives (*urticaria*)*

*Eye infections (*conjunctivitis)

Aching joints (arthralgia)

Potentially severe

Serious infections. Ixekizumab 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. Try to avoid close contact with anyone with a bad cold, influenza or chest infections, and wash your hands frequently when taking this medication.

Blood problems. Some patients in clinical trials were found to have problems producing enough of the blood cells that help to fight infections or stop bleeding.

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

How can the risk of side effects be minimised?

Before you start taking ixekizumab, you will have a thorough consultation with your dermatologist/team including a clinical examination and a number of blood tests. Additional investigations may be required depending on your medical history (for example, a chest Xray or other imaging).
Your dermatologist will go through the below checklist. These situations do not necessarily mean that you cannot be treated with ixekizumab but may mean that other precautions are needed for you to have this treatment safely. Your dermatologist will 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.*
- *Crohn's disease;* if you have active disease or have a history of Crohn's disease or ulcerative colitis.
- 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 routine time points recommended (e.g. with cervical smears, mammograms)

During your treatment with ixekizumab you will be asked about side effects and have blood tests from time to time (for example every 6 months) at your clinic appointments. Keep your own doctor and/or your dermatology team 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 on passing urine, dental problems, night sweats. Your dermatologist may suggest stopping ixekizumab 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 you should make sure that your dermatologist has been informed.

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

Ixekizumab 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 ixekizumab prior to the surgery. Please discuss this with your doctor or dentist.

Can I have immunisations (vaccinations) whilst on ixekizumab?

Patients on ixekizumab 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-Guėrin bacillus (BCG), rotavirus, oral typhoid, varicella (chickenpox). If you require immunisation with a live vaccine, ixekizumab should be stopped for at least 6 months before and until 4 weeks after the vaccination. You should discuss this with your dermatologist.

'Inactivated' or non-live vaccines, such as Pneumovax, Shingrix (for shingles) and the *annual flu vaccine administered by injection*, are safe and recommended. However, you should always check with your healthcare professional when having a vaccination and make them aware that you are on ixekizumab.

Does ixekizumab affect pregnancy?

We do not know the effect of ixekizumab on conception (getting pregnant), on the developing baby or in breastfed babies, and so pregnancy and breastfeeding should be avoided during ixekizumab treatment. The effect of ixekizumab continues for some time after stopping treatment, so it is important that this is taken into account. If you are pregnant or are planning to become pregnant, please discuss with your dermatologist as they will be able to advise on your individual circumstances.

Can I travel abroad while taking ixekizumab?

Please discuss with your dermatologist if you are planning to travel abroad. Depending on where you are travelling, precautions may need to be taken against infections.

May I drink alcohol while taking ixekizumab?

There is no known interaction between alcohol and ixekizumab.

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

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

The BAD Biologic Interventions Register (BADBIR)

You may be asked to take part in a national register if you are prescribed a biologic medication. This register will collect valuable information on side effects and benefits of the drug. It will also inform doctors on how best to use biologic drugs. No information will be passed to the register without your informed consent.

Where can I get more information about ixekizumab?

If you wish to find out more about ixekizumab 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 ixekizumab.

Or visit the emc website to view the patient information leaflet online
https://www.medicines.org.uk/emc/product/8199/pil

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

Psoriasis and Psoriatic Arthritis Alliance (PAPAA)
http://www.papaa.org/

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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