GUSELKUMAB

What are the aims of this leaflet?
This leaflet has been written to help you understand more about guselkumab (Tremfya®). 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 guselkumab and how does it work?
Guselkumab 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 guselkumab can improve symptoms of psoriasis.

What skin conditions are treated with guselkumab?
Guselkumab is used to treat psoriasis.

Why have I been selected for treatment with guselkumab?
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 guselkumab before it has an effect?
Some improvement in your psoriasis may occur in the first few weeks of treatment, but it can take 4 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 4 months. If no significant improvement occurs the treatment will be stopped.

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

Guselkumab must be stored in a refrigerator (between 2 to 8°C). When travelling guselkumab should be kept in a cool box or cool bag with icepacks to maintain the recommended temperature. Once guselkumab has been removed from the refrigerator and has reached room temperature (up to 25°C) it must either be used or thrown away as there is currently no information on how long it can be kept at room temperature – it should not be put back in the refrigerator.

How should I take my medicine?

You will need to give yourself ***one injection*** of guselkumab for the first dose, and then inject the second dose ***4 weeks later.*** After this you should inject ***once every 8 weeks***. If you the psoriasis improves the treatment can be continued to maintain long-term control of your psoriasis.

What are the possible side effects of guselkumab?

Most of the side effects reported during clinical trials of guselkumab 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. Other symptoms may include;

Cold & flu symptoms, sore throat
Stomach flu (gastroenteritis), diarrhoea
Mild fungal infections such as athlete's foot.
Cold sores (herpes simplex infections)
Headaches, rash, hives (urticaria)
Aching joints (arthralgia)

Potentially Severe

Serious infections. Guselkumab 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 infection, and hands should be washed frequently during the course of treatment.

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

How can the risk of side effects be minimised?

Before you start taking guselkumab, 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 checklist below. These situations do not necessarily mean that you cannot be treated with guselkumab 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*
- 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. cervical smears, mammograms).

During your treatment with guselkumab 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 guselkumab 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?
Guselkumab 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 guselkumab prior to the surgery. Please discuss this with your doctor or dentist.
Can I have immunisations (vaccinations) whilst on guselkumab?

Patients on guselkumab 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) and herpes zoster (shingles). If you require immunisation with a live vaccine, guselkumab should be stopped for at least 12 weeks before (12 months in the case of shingles vaccine) and until 2 weeks after the vaccination. You should discuss this with your dermatologist.

'Inactivated' vaccines (e.g. Pneumovax 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 guselkumab.

Does guselkumab affect pregnancy?
We do not know the effect of guselkumab on conception (getting pregnant), on the developing baby or in breastfed babies, and so pregnancy and breastfeeding should be avoided during guselkumab treatment. The effect of guselkumab 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 guselkumab?
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 guselkumab?
There is no known interaction between alcohol and guselkumab.

Can I take other medicines at the same time as guselkumab?
Most medicines are safe to take with guselkumab. 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 guselkumab?
This information sheet does not list all of the side effects of guselkumab. If you wish to find out more about guselkumab 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 guselkumab.

Or visit the emc website to view the patient information leaflet online
https://www.medicines.org.uk/emc/product/8662/pil

Or visit the website www.tremfya.com/

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