SOME USEFUL INFORMATION ABOUT YOUR BIMZELX TREATMENT

This patient information leaflet is intended for adult patients who have been prescribed Bimzelx (bimekizumab) for the treatment of moderate to severe plaque psoriasis.

Bimekizumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of plaque psoriasis.

The following information does not replace the Patient Information Leaflet (PIL) and Instructions for Use (IFU) that come with your medication. Please read the PIL and IFU carefully before starting treatment.
What is bimekizumab and how does it work?¹

Bimzelx contains the active substance bimekizumab. It is a biologic medicine that has been designed to treat moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Bimekizumab belongs to a group of medicines called interleukin (IL) inhibitors and works by reducing the activity of two proteins called IL-17A and IL-17F, which are involved in causing inflammation. There are higher levels of these proteins in inflammatory diseases such as psoriasis.

What skin conditions are treated with bimekizumab?¹

Bimekizumab is used to treat moderate to severe plaque psoriasis. The treatment reduces symptoms, including pain, itching, and scaling of the skin.

Why have I been selected for treatment with bimekizumab?¹

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 bimekizumab before it has an effect?¹ ²

Some improvement in your psoriasis may occur in the first few weeks of treatment but it can take 16 weeks to see the full benefit. In clinical trials, more than 8 out of 10 patients had achieved at least a 90% improvement in their psoriasis by 16 weeks. If no significant improvement occurs the treatment will be stopped.
How do I take bimekizumab?1

Bimekizumab is given as an injection under your skin (subcutaneously). It is delivered as either a pre-filled syringe which you manually inject, or a pen device which automatically injects the drug. Your doctor will help you decide which device is best suited for you.

If you will be giving your own injections, a nurse or a doctor will demonstrate the correct technique to you. Injections are made under the skin of the stomach or thighs; the back of your arm may also be used if a doctor or nurse is giving you the injection.

You will be provided with a special bin so that you can dispose of your syringes safely.

Bimekizumab must be stored in a refrigerator (between 2 to 8°C). Do not freeze.

Once bimekizumab has been removed from the refrigerator and has reached room temperature (up to 25°C) it can be kept for a maximum of 25 days providing it is kept in the outer carton and kept out of direct light.

If bimekizumab is kept out of the refrigerator for longer than this or exposed to a temperature above 25°C it must be thrown away.

Keep your medicine out of the sight and reach of young children.

How often should bimekizumab be taken?1

Each syringe contains 160mg of bimekizumab, therefore you will need to inject TWO injections (total dose 320mg) at weeks 0, 4, 8, 12, 16.

From week 16, you will use 320 mg (two injections, containing 160 mg each) every 8 weeks.

If you weigh 120 kg or more, and have not achieved complete skin clearance by week 16, your doctor may decide to continue your injections every 4 weeks from week 16.
What are the possible side effects of bimekizumab?¹

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor, pharmacist or nurse if you get any of the following side effects:

**Very common** (may affect more than 1 in 10 people)
- upper respiratory infections with symptoms such as sore throat and stuffy nose

**Common** (may affect up to 1 in 10 people)
- thrush in the mouth or throat with symptoms such as white or yellow patches; red or sore mouth and pain with swallowing
- fungal infection of the skin, such as athlete’s foot between the toes
- ear infections
- cold sores (herpes simplex infections)
- stomach flu (gastroenteritis)
- inflamed hair follicles which may look like pimples
- headache
- itchy, dry skin or an eczema-like rash sometimes with swollen and reddened skin (dermatitis)
- acne
- redness, pain or swelling at the site of injection
- feeling tired

**Uncommon** (may affect up to 1 in 100 people)
- lowered levels of white blood cells (neutropenia)
- fungal infections of the skin and mucous membranes (including oesophageal candidiasis)
- discharge from the eye with itching, redness and swelling (conjunctivitis)
- blood in the stool, abdominal cramps and pain, diarrhoea or weight loss (signs of bowel problems)

**Serious side effects**

Tell your doctor or get medical help immediately if you get any of the following side effects, as they may indicate that you have a serious infection:
- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters
What you need to know before you start bimekizumab:¹

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

- you have an infection or an infection that keeps coming back.
- you recently had or plan to have a vaccination. You should not be given certain types of vaccines (live vaccines) while using bimekizumab.
- you have ever had tuberculosis (TB).
- you have ever had inflammatory bowel disease (Crohn’s disease or ulcerative colitis).

Do not use bimekizumab
- if you are allergic to bimekizumab or any of the other ingredients of this medicine
- if you have an infection, including tuberculosis (TB), which your doctor thinks is important.

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

Bimekizumab may increase your risk of getting an infection after a surgical procedure. You must tell the doctor or dentist that you are taking bimekizumab.

Can I have immunisations (vaccinations) whilst on bimekizumab?¹ ²

You should not be given certain types of vaccines (live vaccines) while using bimekizumab. Talk to your doctor if you have recently had or plan to have a vaccination.

Does bimekizumab affect pregnancy and breast-feeding?¹

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking bimekizumab. It is preferable to avoid the use of bimekizumab in pregnancy. This is because it is not known how this medicine will affect the baby.

If you are a woman who can become pregnant, you should use contraception while using bimekizumab and for at least 17 weeks after your last dose of bimekizumab.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using bimekizumab. You and your doctor should decide if you can breast-feed or use bimekizumab.
Additional Information:
You can access additional patient information at www.mybimzelx-psco.co.uk
To access, please use the following brochure code: BKZ00001

This medicine is subject to additional monitoring. This will allow quick identification of new safety information.

You can help by reporting any side effects you may get. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient information leaflet. You can also report side effects directly via the Yellow Card Scheme website: https://yellowcard.mhra.gov.uk

You can also report adverse events to UCB at UCBCares.UK@ucb.com

References: