Bimzelx (Bimekizumab)

What is Bimzelx?

Bimzelx (also referred to by its generic name, bimekizumab) is a biologic medication approved by the Medicines and Healthcare products Regulatory Agency (MHRA). It is recommended by the National Institute for Health and Care Excellence (NICE) and the Scottish Medicines Consortium (SMC) to treat severe psoriasis (or if you cannot take, or if your psoriasis has not responded well to systemic treatments including ciclosporin, methotrexate and phototherapy) in England, Wales and Scotland.

Bimzelx is also recommended by the National Institute for Health and Care Excellence (NICE) to treat active psoriatic arthritis (PsA) in adults whose condition has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them.

This medication is taken via a pre-filled pen injection.

How does Bimzelx work?

Bimzelx belongs to a group of medicines called interleukin (IL) inhibitors. The active ingredient in Bimzelx is Bimekizumab which works by reducing the activity of two proteins called interleukin-17A (IL-17A) and interleukin-17 F (IL-17F), which are involved in causing inflammation and the symptoms of psoriasis or PsA. IL-17A and IL-17F are also involved in the body's immune responses. People with psoriasis or PsA have higher levels of both these proteins than people without psoriasis or PsA. By binding to IL-17 A and IL-17F, Bimzelx interrupts their activity (i.e. stops them from working as they usually would). This means that Bimzelx disturbs the inflammatory cycle of psoriasis or PsA, which can lead to the improvement in symptoms such as pain, itching and scaling of the skin for many people who take it.

Because of the effect Bimzelx has on the immune system, you will be monitored for infections throughout your treatment, and you will be tested for Tuberculosis (TB), including latent (hidden) TB before starting treatment. People taking Bimzelx may need an annual flu jab but should check with a doctor or nurse before having any other vaccinations or taking other medication.

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Who is Bimzelx for?

Bimzelx is for adults with severe plaque psoriasis who have not had a good response from, or cannot tolerate other systemic treatments including ciclosporin, methotrexate and phototherapy. You will usually need to have tried these treatments before you can be offered Bimzelx. If you have tried these treatments and they did not work, Bimzelx might be an option for you.

Bimzelx can also be prescribed for adults with active psoriatic arthritis if other disease-modifying anti-rheumatic drugs (DMARDs) have not worked or cannot be tolerated. You may be offered Bimzelx to treat psoriatic arthritis if you have already tried systemic treatments such as methotrexate, sulfasalazine or leflunomide, and have tried at least one biologic treatment such as etanercept, adalimumab, infliximab, or Simponi, or you are unable to take an anti-TNF alpha biologic (such as etanercept, adalimumab, infliximab, or Simponi).

Who should not take Bimzelx?

- People with active serious infections. You will be tested to check for infections before starting treatment.
- If you are allergic to Bimzelx or any of the other ingredients of the medicine.
- If you are planning to have children, are currently pregnant, or are planning breastfeeding, please discuss this with your doctor before taking Bimzelx. There is little evidence available at present for the effects of Bimzelx in pregnant women.
- Caution is advised in people with Inflammatory Bowel Disease (Crohn's Disease or Ulcerative Colitis) as Bimzelx has been shown to exacerbate (make worse) Inflammatory Bowel Disease in some cases.
- You should always check with your doctor or nurse before taking any other medication with Bimzelx. Certain types of vaccines (live vaccines) cannot be given while using Bimzelx.
- Children or adolescents (under 18 years of age) because Bimzelx has not been studied in this age group.

How is Bimzelx used?

Bimzelx is taken as an injection under the skin, either via a pre-filled syringe or a pre-filled pen device. The dose can vary depending on weight. Your Dermatologist, Rheumatologist or Specialist Nurse will discuss your dose with you.

Most people will be trained by a nurse to administer the injection themselves. In the first 16 weeks, your prescribed dose should be taken once, every 4 weeks. After that, doses are usually

taken every 8 weeks for psoriasis and every 4 weeks for PsA. Each dose for treating psoriasis is made up of 2 injections. Each dose for treating PsA is made up of 1 injection.

People taking Bimzelx are likely to need regular blood tests - usually carried out by the Dermatology or Rheumatology departments or by your own GP, to monitor for infections or other possible effects of the treatment.

If an adequate response is not seen after 16 weeks of using Bimzelx, the treatment will be stopped. However, if you are taking Bimzelx to treat PsA and there has not been an adequate response after 16 weeks, but there is a good response in your skin psoriasis, then it is possible to continue using Bimzelx following an assessment by a Dermatologist.

Bimzelx must be stored in a refrigerator (between 2 to 8°C). Once Bimzelx 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 Bimzelx is kept out of the refrigerator for longer than this or exposed to a temperature above 25°C it must be thrown away.

What are the side effects?

As with all medications, some side effects are possible when taking Bimzelx. It is important to remember that not every person taking a medication will get all, or even any, of the possible side effects listed. Many side effects of Bimzelx are mild, or can be managed with other medications, and do not cause most people to stop taking it. Bimzelx is a new treatment and, as such, this side effect data comes from clinical trials, but will be updated as more 'real-world' experience with the treatment is collected.

The most common side effects reported include upper respiratory tract infections, headache, tiredness, thrush in the mouth or throat, fungal infections of the skin, ear infections, itchy dry skin or a rash, acne and stomach flu (gastroenteritis). If you experience these side effects, tell your Dermatologist, Rheumatologist or Specialist Nurse.

Your Dermatologist, Rheumatologist or Specialist Nurse will explain the potential side effects of Bimzelx to you and explain how to look for signs of a serious infection (these include fever, flu-like symptoms, night sweats, feeling tired or short of breath, a cough that does not go away or warm, red and painful skin, or a painful skin rash with blisters). If you experience these symptoms, you should report them to your Dermatology or Rheumatology Team immediately.

For a full list of potential side effects please speak to your Dermatologist, Rheumatologist or Pharmacist, or refer to the Patient Information Leaflet that comes with the Bimzelx injection.

How long will Bimzelx take to work?

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. If considerable improvement is not seen in 16 weeks, improvement with Bimzelx will be stopped. If this happens, your Dermatologist or Rheumatologist should discuss the next available options with you – there are a number of other biologic or systemic treatments that can be tried if Bimzelx does not work.

Can I have immunisations (vaccinations) whilst on Bimzelx?

It is important that when having vaccinations, you check with your Dermatology or Rheumatology team as to whether you need to stop or delay taking Bimzelx as they will have the most up-to-date advice regarding the continuing of your treatment at this time. If you are taking Bimzelx, you should not receive a live vaccine (e.g. chicken pox vaccine).

How safe and effective is Bimzelx?

Bimzelx is a new medication to treat moderate to severe psoriasis that was approved for use in England and Wales in September 2021 and Scotland in November 2021. 'Real-world' (i.e. non-clinical trial) safety and effectiveness data is being collected by a long-running study, the British Association of Dermatologists Biologics and Immunomodulators Register (BADBIR). It is recommended that all people taking biologic treatments for their psoriasis should be asked for their information to be included in this register.

For more information on BADBIR, please see the website: www.badbir.org

The information in this resource is not intended to replace that of a healthcare professional. If you have any concerns or questions about your treatment, do discuss this with your doctor and always read the patient information leaflet to make sure you are using them correctly.
For more information, or for a list of resources used in producing this information sheet, please contact the Psoriasis Association

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