



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/432519/2021
EMA/H/C/005316

Bimzelx (*bimekizumab*)

An overview of Bimzelx and why it is authorised in the EU

What is Bimzelx and what is it used for?

Bimzelx is a medicine used to treat plaque psoriasis, a disease that causes red, scaly patches on the skin. It is used in adults with moderate to severe disease who need systemic treatment (treatment with medicines affecting the whole body).

Bimzelx contains the active substance bimekizumab.

How is Bimzelx used?

Bimzelx can only be obtained with a prescription, and it should be used under the supervision of a doctor experienced in diagnosing and treating psoriasis.

Bimzelx is available as an injection in pre-filled syringes or pen injectors. It is given as an injection under the skin. Two injections of 160 mg each (a total of 320 mg) are given once every four weeks for 16 weeks. After that, injections are usually given every eight weeks. The doctor may decide to stop the treatment if the condition does not improve after 16 weeks.

Patients can inject Bimzelx themselves once they have been trained to do so.

For more information about using Bimzelx, see the package leaflet or contact your doctor or pharmacist.

How does Bimzelx work?

The active substance in Bimzelx, bimekizumab, is a monoclonal antibody, a protein designed to attach to interleukins IL-17A, IL-17F and IL-17AF, which are messenger molecules in the body's immune system (the body's natural defences). High levels of these interleukins have been shown to be involved in developing inflammatory diseases caused by the immune system, such as plaque psoriasis. By attaching to these interleukins, bimekizumab prevents them from interacting with their receptors (targets) on the surface of the epidermis (outer layer of the skin), which reduces inflammation and improves the symptoms related to plaque psoriasis.

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What benefits of Bimzelx have been shown in studies?

Three main studies showed that Bimzelx was effective in treating adult patients with moderate to severe plaque psoriasis. Plaque psoriasis improved to a greater extent in patients treated with Bimzelx than in those treated with placebo (a dummy treatment) or with two other medicines for psoriasis (ustekinumab or adalimumab).

In the three studies involving 1,480 patients in total, around 85 to 91% of those receiving Bimzelx every four weeks achieved a reduction of about 90% in PASI scores (a measure of psoriasis severity and affected skin area) after 16 weeks. This compares with 1 to 5% of patients receiving placebo (in two of the studies), 50% of those receiving ustekinumab (in one of the studies), and 47% of those receiving adalimumab (in one of the studies).

Also, 84 to 93% of patients receiving Bimzelx had clear or nearly clear skin after 16 weeks, compared with 1 to 5% of patients receiving placebo, 53% of patients receiving ustekinumab and 57% of patients receiving adalimumab.

What are the risks associated with Bimzelx?

The most common side effects with Bimzelx are upper respiratory tract infections (nose and throat infection), which may affect more than 1 in 10 people, and oral candidiasis (thrush, a fungal infection in the mouth or throat), which may affect up to 1 in 10 people. The medicine must not be given to patients with a significant ongoing infection, such as active tuberculosis.

For the full list of side effects and restrictions with Bimzelx, see the package leaflet.

Why is Bimzelx authorised in the EU?

Studies have shown that Bimzelx is an effective treatment for patients with moderate to severe plaque psoriasis. The positive effects of the medicine were maintained with continued use for up to one year. The side effects were in line with other similar psoriasis medicines, with the most important side effect being nose and throat infections, as well as candidiasis (a yeast [fungal] infection) in the mouth or throat.

The European Medicines Agency therefore decided that Bimzelx's benefits are greater than its risks, and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Bimzelx?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Bimzelx have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Bimzelx are continuously monitored. Suspected side effects reported with Bimzelx are carefully evaluated and any necessary action taken to protect patients.

Other information about Bimzelx

Bimzelx received a marketing authorisation valid throughout the EU on 20 August 2021.

Further information on Bimzelx can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/bimzelx.

This overview was last updated in 08-2021.