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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 the following inflammatory diseases:

- moderate-to-severe plaque psoriasis (red, scaly patches on the skin) in adults who need systemic treatment (treatment with medicines affecting the whole body);
- psoriatic arthritis (inflammation of the joints that often accompanies plaque psoriasis) in adults whose disease does not respond well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot take these medicines. For psoriatic arthritis, Bimzelx is used alone or with methotrexate;
- axial spondyloarthritis (inflammation of the spine causing back pain) in adults whose disease does not respond well enough to conventional treatments. For this condition, it is used in patients who have signs of disease on X-rays (radiographic axial spondyloarthritis) as well as in patients who have clear signs of inflammation but no signs of disease on X-rays (non-radiographic axial spondyloarthritis);
- hidradenitis suppurativa (acne inversa), a long-term skin disease that causes painful lumps, abscesses (collections of pus), fistulas (tunnels under the skin) and scarring on the skin. It is used in adults with moderate-to-severe active disease when conventional systemic treatments do not work well enough.

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, psoriatic arthritis, axial spondyloarthritis and hidradenitis suppurativa.

Bimzelx is given as an injection under the skin. For plaque psoriasis and psoriatic arthritis accompanying plaque psoriasis, the medicine is given as one or two injections every 4 weeks for 16 weeks and every 8 weeks thereafter. For hidradenitis suppurativa, it is given as one or two injections every 2 weeks for 16 weeks and every 4 weeks after that.

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For psoriatic arthritis alone and axial spondyloarthritis, Bimzelx is given as one injection every 4 weeks.

The doctor may decide to stop the treatment if these conditions do 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 type of 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, psoriatic arthritis, axial spondyloarthritis and hidradenitis suppurativa. By attaching to these interleukins, bimekizumab prevents them from interacting with their receptors (targets) within the body, which reduces inflammation and improves the symptoms related to these diseases.

What benefits of Bimzelx have been shown in studies?

Plaque psoriasis

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.

Psoriatic arthritis

In two main studies of around 1,100 patients with psoriatic arthritis, including patients who were taking methotrexate, Bimzelx was effective at reducing symptoms as measured using a standard metric known as ACR50. Patients achieving an ACR50 response have at least a 50% improvement in symptoms scores for joint pain and swelling.

Taken together, the results from the two studies showed that 44% of patients treated with Bimzelx achieved a ACR50 response after 16 weeks compared with 9% of those treated with placebo (a dummy treatment).

Axial spondyloarthritis

Two main studies in patients with axial spondyloarthritis showed that Bimzelx was effective at reducing symptoms as measured using a standard metric known as ASAS40 after 16 weeks. Patients achieving an ASAS40 response have at least a 40% improvement in scores for symptoms such as pain and inflammation.

In one of the studies, which involved 254 patients with non-radiographic axial spondyloarthritis, 48% of patients treated with Bimzelx achieved an ASAS40 response compared with 21% of patients treated with placebo (a dummy treatment).

In the second study which involved 332 patients with radiographic axial spondyloarthritis, 45% of patients treated with Bimzelx achieved an ASAS40 response compared with 23% of patients treated with placebo.

Hidradenitis suppurativa

In two main studies in over 1,000 adults with hidradenitis suppurativa, 50% of patients using Bimzelx achieved a reduction of at least 50% in the overall number of abscesses and lumps after 16 weeks, without any increase in the number of abscesses or fistulas. The proportion of patients given placebo who achieved this response was 31%.

What are the risks associated with Bimzelx?

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

The most common side effects with Bimzelx include 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.

Why is Bimzelx authorised in the EU?

Studies have shown that Bimzelx is an effective treatment for patients with moderate-to-severe plaque psoriasis, psoriatic arthritis, axial spondyloarthritis and hidradenitis suppurativa. The positive effects of the medicine were maintained with continued use for up to one year. The side effects were comparable to those of other similar medicines, with the most important side effects being nose and throat infections, and thrush.

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 is 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 07-2024.