swissmedic

Summary report on authorisation dated 8 May 2026

Bimzelx® (active substance: bimekizumab)

Indication extension in Switzerland: 13 January 2026

Solution for injection in a pre-filled syringe or pre-filled pen for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults

About the medicinal product

The medicinal product Bimzelx contains the active substance bimekizumab.

Bimzelx was first authorised on 27 October 2022 for the treatment of the skin disease plaque psoriasis in adults.

On 29 July 2024, an indication extension for Bimzelx was authorised for the treatment of axial spondyloarthritis, including non-radiographic axial spondyloarthritis and ankylosing spondylitis (radiographic axial spondyloarthritis) in adults.

On the same date, a further indication extension for Bimzelx, for the treatment of psoriatic arthritis in adults, was also authorised.

Under the present indication extension, Bimzelx can be used to treat active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to systemic antibiotic therapy.

Hidradenitis suppurativa is a chronic skin disease characterised by painful, inflamed nodules and abscesses, particularly in skin folds such as the underarms or groin.

In deciding whether to authorise this indication extension for the medicinal product Bimzelx, Swissmedic took into account the assessments of the European Medicines Agency (EMA) as well as the corresponding medicinal product information texts issued by EMA and the US Food and Drug Administration (FDA).

Mode of action

Bimekizumab, the active substance in Bimzelx, blocks certain proteins that can trigger inflammation. By blocking these proteins, Bimzelx can help alleviate symptoms and improve skin lesions by reducing inflammation. This can help relieve pain.

Administration

Bimzelx is a prescription-only medicine.

Bimzelx is available as a solution for injection in a pre-filled pen and pre-filled syringe in dosage strengths of 160 mg and 320 mg.

The recommended dose for adults for the treatment of hidradenitis suppurativa is 320 mg (administered as two 160 mg injections beneath the skin (subcutaneous) or one 320 mg injection beneath the skin) every two weeks until week 16, and then every four weeks.

Efficacy

The efficacy of Bimzelx in the treatment of moderate to severe hidradenitis suppurativa was investigated in two studies (HS0003 and HS0004) involving a total of 1,014 patients. The participants were at least 18 years of age with a diagnosis of at least six months and a history of inadequate response to antibiotics. They were divided into four treatment groups and received either 320 mg Bimzelx every two weeks, 320 mg Bimzelx every four weeks, a combination of both dosages or placebo (dummy drug). Both studies showed that patients who received Bimzelx experienced fewer abscesses and inflammatory nodules than patients who received placebo.

Precautions, undesirable effects, & risks

Bimzelx must not be used in those who are hypersensitive to the active substance or any of the excipients.

The medicinal product may trigger allergic reactions. Immediate medical assistance must be sought if severe symptoms occur.

The most common undesirable effects (affecting more than one in ten users) are upper respiratory infections.

All precautions, risks, and other possible undesirable effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

Treatment options for hidradenitis suppurativa are currently limited and the response to antibiotics is often inadequate.

The studies showed that the course of the disease was improved in patients who received Bimzelx, owing to the reduction in abscesses and inflammatory nodules.

Taking all the risks and precautions into account, and based on the available data, the benefits of Bimzelx outweigh the risks. Swissmedic has therefore authorised the indication extension for the medicinal product Bimzelx, containing the active substance bimekizumab, for the treatment of Hidradenitis suppurativa in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Bimzelx®

Information for patients (package leaflet): Information for patients Bimzelx®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.