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EPAR summary for the public

Taltz

ixekizumab

This is a summary of the European public assessment report (EPAR) for Taltz. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Taltz.

For practical information about using Taltz, patients should read the package leaflet or contact their doctor or pharmacist.

What is Taltz and what is it used for?

Taltz is a medicine used for treating moderate to severe plaque psoriasis, a disease causing red, scaly patches on the skin. It is used in adults who require systemic treatment (treatment with medicines affecting the whole body).

Taltz contains the active substance ixekizumab.

How is Taltz used?

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

Taltz is available as an injection in pre-filled syringes and in pen injectors. It is given as an injection under the skin. The first dose of 160 mg (two injections) is followed by an injection of 80 mg every two weeks for the first 12 weeks and every 4 weeks thereafter. The doctor may decide to stop treatment if the condition does not improve after 16 to 20 weeks. After training, patients may inject Taltz if their doctor considers it appropriate. For further information, see the summary of product characteristics (also part of the EPAR).

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How does Taltz work?

The active substance in Taltz, ixekizumab, is a monoclonal antibody, a protein designed to attach to interleukin 17A, a messenger molecule in the body's immune system (the body's natural defences). Interleukin 17A is involved in immune system effects, including inflammation, that cause psoriasis. By attaching to interleukin 17A, ixekizumab blocks its action and reduces the activity of the immune system and thereby reduces the symptoms of psoriasis.

What benefits of Taltz have been shown in studies?

Studies show that Taltz is effective in treating plaque psoriasis in patients who required systemic treatment. Plaque psoriasis improved to a greater extent in patients treated with Taltz than with placebo (a dummy treatment) or with etanercept, another medicine used to treat psoriasis.

In 3 main studies involving over 3,800 patients with psoriasis, 89% of those treated every two weeks with Taltz attained a 75% reduction in PASI scores (a measure of disease severity and area of skin affected) after 12 weeks. This compares with 4% of those given placebo and with 48% of patients given etanercept in 2 of the main studies. Also, 82% of patients given Taltz had clear or nearly clear skin after 12 weeks, compared with 4% of patients given placebo and 39% of patients given etanercept

In 2 studies, treatment was continued in patients whose psoriasis improved with Taltz given every 2 weeks for 12 weeks. After further treatment with Taltz every 4 weeks for 48 weeks, 78% of patients had clear or nearly clear skin.

What are the risks associated with Taltz?

The most common side effects with Taltz (which may affect more than 1 in 10 people) are pain and redness at the injection site, and nose, throat or chest infections. Taltz must not be given to patients who have potentially serious infections such as tuberculosis. For the full list of all side effects and restrictions with Taltz, see the package leaflet.

Why is Taltz approved?

The Agency’s Committee for Medicinal Products for Human Use (CHMP) decided that Taltz’s benefits are greater than its risks and recommended that it be approved for use in the EU. The medicine has been shown to be effective in moderate to severe plaque psoriasis and its side effects are in line with other similar psoriasis medicines.

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

A risk management plan has been developed to ensure that Taltz is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Taltz, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Taltz

The European Commission granted a marketing authorisation valid throughout the European Union for Taltz on 25 April 2016.

The full EPAR and risk management plan summary for Taltz can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Taltz, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 04-2015.