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# Taltz (ixekizumab)

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

## What is Taltz and what is it used for?

Taltz is a biological medicine used to treat several inflammatory conditions.

**Plaque psoriasis**

Taltz is used to treat people aged 6 years and older weighing at least 25 kg with moderate-to-severe plaque psoriasis, a disease causing red, scaly patches on the skin. It is used when people require systemic treatment (treatment with medicines affecting the whole body).

**Psoriatic arthritis**

Taltz is used to treat adults and children aged 6 years and older weighing at least 25 kg with psoriatic arthritis (when psoriasis causes inflammation of the joints) whose disease is causing symptoms and has not improved sufficiently with other medicines called disease-modifying anti-rheumatic drugs (DMARDs) or who cannot use them. Taltz is used alone or with another medicine called methotrexate (a medicine that acts on the immune system).

**Axial spondyloarthritis**

Taltz is used to treat adults with axial spondyloarthritis, an inflammation of the spine causing back pain and stiffness.

It can be used in people with the radiographic form of the disease, also called ankylosing spondylitis (when bone damage is visible on X-rays), and when standard treatments have not worked well enough.

It can also be used in those with the non-radiographic form (where no bone damage is visible on X-rays) who show signs of inflammation, such as elevated levels of C-reactive protein (CRP) or signs seen on magnetic resonance imaging (MRI), and for whom non-steroidal anti-inflammatory drugs (NSAIDs) have not worked well enough.

**Enthesitis-related arthritis**

Taltz is used to treat children aged 6 years and older who weigh at least 25 kg with enthesitis-related arthritis, when their condition has not improved sufficiently with standard treatments or who cannot

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use them. Enthesitis-related arthritis is an inflammation of the joints and entheses (areas where tendons and ligaments attach to bone). Taltz is used alone or with methotrexate.

Taltz contains the active substance ixekizumab.

## How is Taltz used?

Taltz can only be obtained with a prescription. It should be used under the supervision of a doctor experienced in diagnosing and treating people with the condition it is used for.

Taltz is given by injection under the skin using a pre-filled syringe or pen. The number of injections and how often they are given depend on the person's age and the condition being treated. Patients and their caregivers may inject Taltz themselves if their doctor considers it appropriate and they have received training.

If no improvement is seen after 16 to 20 weeks of treatment, the doctor may decide to stop treatment.

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

## How does Taltz work?

The active substance in Taltz, ixekizumab, is a protein called a monoclonal antibody. It works by attaching to another protein called interleukin 17A, which plays a key role in causing inflammation in people with plaque psoriasis, psoriatic arthritis, axial spondyloarthritis and enthesitis-related arthritis. By blocking interleukin 17A, ixekizumab helps reduce the activity of the immune system (the body's natural defences) and the symptoms of these inflammatory conditions.

## What benefits of Taltz have been shown in studies?

### Plaque psoriasis

Studies showed that Taltz is effective in treating plaque psoriasis in adults and children aged 6 years and older who required systemic treatment.

In 3 main studies involving over 3,800 adults with plaque psoriasis who required systemic treatment, 89% of those treated with Taltz achieved a 75% reduction in their PASI score (a measure of how severe the disease is and how much of the skin is affected) after 12 weeks. This compares with 4% of those given placebo (a dummy treatment) and 48% of those given another medicine called etanercept in two of the main studies. Additionally, 82% of people given Taltz had their skin clear or almost clear of plaque psoriasis after 12 weeks, compared with 4% of those given placebo and 39% of those given etanercept. In two of the studies, participants whose plaque psoriasis had improved continued treatment with Taltz beyond 12 weeks. After 48 weeks of treatment, 78% of the participants had their skin clear or almost clear of psoriasis.

An additional study involved 201 children aged 6 years and older with moderate-to-severe plaque psoriasis who required systemic treatment. After 12 weeks of treatment, around 89% (102 out of 115) of children given Taltz achieved a 75% reduction in their PASI score, compared with 25% (14 out of 56) of those given placebo. In addition, around 81% (93 out of 115) of children given Taltz had their skin clear or almost clear of psoriasis, compared with around 11% (6 out of 56) of those given placebo.

### Psoriatic arthritis

Two main studies involving 780 adults with psoriatic arthritis showed that Taltz is more effective than placebo in treating the condition. Effectiveness was measured by the number of people who had a 20% improvement in signs and symptoms of the disease (ACR20) after 24 weeks of treatment.

In the first study, which involved adults who had not been treated with biological medicines before, Taltz was effective in 58% (62 out of 107) of people. This compares with 30% (32 out of 106) of those given placebo and 57% (58 out of 101) given another medicine called adalimumab. The second study looked at patients whose condition had not improved with other medicines or who had unacceptable side effects with them. It found that 53% (65 out of 122) of participants improved with Taltz compared to 20% (23 out of 118) with placebo.

**Axial spondyloarthritis**

Taltz was shown to be effective in treating radiographic and non-radiographic axial spondyloarthritis in three main studies.

The first study involved 341 adults with radiographic axial spondyloarthritis who had not been treated with DMARDs before. After 16 weeks of treatment, around 48% (39 out of 81) of those given Taltz had at least a 40% improvement in signs and symptoms (ASAS40), compared with around 36% (32 out of 90) of those given adalimumab and 18% (16 out of 87) of those given placebo.

The second study involved 316 adults with radiographic axial spondyloarthritis who had previously been treated with other medicines called TNF inhibitors. After 16 weeks of treatment, around 25% (29 out of 114) of those given Taltz achieved a 40% improvement, compared with around 13% (13 out of 104) of those given placebo.

The third study involved 303 adults with non-radiographic axial spondyloarthritis who had not received DMARDs before. After 16 weeks of treatment, around 35% (34 out of 96) of participants given Taltz achieved a 40% improvement, compared with 19% (20 out of 105) given placebo.

**Psoriatic arthritis and enthesitis-related arthritis in children**

In a main study involving 101 children aged 5 years and older, Taltz was effective in treating psoriatic arthritis and enthesitis-related arthritis. The study measured how many participants had at least a 30% improvement in the signs and symptoms of their condition (ACR30).

After 16 weeks of treatment, around 89% (72 out of 81) of children given Taltz had at least a 30% improvement. In addition, 79% (64 out of 81) of children treated with Taltz had at least a 50% improvement (ACR50), and around 64% (52 out of 81) had at least a 70% improvement (ACR70).

## What are the risks associated with Taltz?

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

The most common side effects with Taltz (which may affect more than 1 in 10 people) include pain and redness at the injection site, and nose and throat infections.

Taltz must not be given to patients who have serious infections such as tuberculosis.

## Why is Taltz authorised in the EU?

Studies showed that Taltz is effective in treating moderate-to-severe plaque psoriasis, psoriatic arthritis, axial spondyloarthritis and enthesitis-related arthritis.

Regarding safety, the side effects of Taltz are in line with those of other medicines used to treat these diseases.

The European Medicines Agency therefore decided that Taltz'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 Taltz?

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

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

## Other information about Taltz

Taltz received a marketing authorisation valid throughout the EU on 25 April 2016.

Further information on Taltz can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/taltz.

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