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**EPAR summary for the public**

# Cosentyx

secukinumab

This is a summary of the European public assessment report (EPAR) for Cosentyx. 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 Cosentyx.

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

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

Cosentyx is an anti-inflammatory medicine used to treat adult patients with:

- moderate to severe plaque psoriasis (a disease causing red, scaly patches on the skin) when the patient needs systemic (whole body) treatment;
- psoriatic arthritis (inflammation of the joints associated with psoriasis) when disease-modifying anti-rheumatic drugs (DMARDs) do not work well enough;
- ankylosing spondylitis (a disease causing inflammation and pain in the joints of the spine) when conventional treatments do not work well enough.

It contains the active substance secukinumab.

## How is Cosentyx used?

Cosentyx can only be obtained with a prescription and treatment should only be given under the supervision of a doctor with experienced in diagnosing and treating the conditions for which Cosentyx is used.

The medicine is available as a powder used to make a solution for injection, or as a ready-to-use solution in a pre-filled syringe or pen injector. Cosentyx is given by injection under the skin as four

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weekly injections followed by monthly maintenance injections. The dose to be used depends on the disease to be treated. An improvement is usually seen within 16 weeks of treatment. The doctor should consider stopping treatment if no improvement has been seen during this time. Some patients with an initial partial improvement may see further improvements with continued treatment beyond 16 weeks. For further information, see the package leaflet.

## How does Cosentyx work?

The active substance in Cosentyx, secukinumab, is a monoclonal antibody, a type of protein, designed to recognise and attach to a messenger molecule in the immune system called interleukin 17A. This molecule is involved in the inflammation and other immune system processes that cause psoriasis and are involved in psoriatic arthritis and ankylosing spondylitis. By attaching to and blocking the action of interleukin 17A, secukinumab reduces the activity of the immune system and the symptoms of the disease.

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

Studies showed that Cosentyx is effective in treating psoriasis, psoriatic arthritis and ankylosing spondylitis, with patients showing greater improvements with Cosentyx than with placebo (a dummy treatment) or with a comparator medicine, etanercept.

In 4 psoriasis studies involving 2,403 patients, 79% of those on Cosentyx achieved a 75% reduction in their PASI scores (a measure of disease severity and area of skin affected) after 12 weeks of treatment. This compares with 44% of those on a comparator medicine etanercept and 4% of those on placebo. In addition, 65% of patients given Cosentyx had clear or nearly clear skin, compared with 27% of patients given etanercept and 2% of those given placebo.

In a study of 397 patients with psoriatic arthritis, between 51% and 54% of patients on the approved doses of Cosentyx achieved a 20% reduction in ACR scores (painful, swollen joints and other symptoms) after 24 weeks. This compares with 15% of patients on placebo.

Finally, in a study of 219 patients with ankylosing spondylitis, 61% of patients given the approved dose of Cosentyx achieved a 20% reduction in ASAS scores (back pain, morning stiffness and other symptoms) after 16 weeks, compared with 28% of patients on with placebo.

## What are the risks associated with Cosentyx?

The most common side effects with Cosentyx (which may affect more than 1 in 10 people) are upper respiratory tract infections (colds) with inflammation of the nose and throat (nasopharyngitis) and blocked or runny nose (rhinitis). Most of the side effects are mild to moderate in severity. Because Cosentyx may increase the risk of infection, it must not be given to patients with serious active infections such as tuberculosis.

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

## Why is Cosentyx approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Cosentyx'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 of substantial clinical benefit in patients with psoriasis, psoriatic arthritis and ankylosing spondylitis. The safety profile was considered reassuring, with the main concern related to mild infections.

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

A risk management plan has been developed to ensure that Cosentyx 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 Cosentyx, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

## Other information about Cosentyx

The European Commission granted a marketing authorisation valid throughout the European Union for Cosentyx on 15 January 2015.

The full EPAR and risk management plan summary for Cosentyx 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 Cosentyx, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2015.