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Cosentyx (*secukinumab*)

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

What is Cosentyx and what is it used for?

Cosentyx is a medicine that acts on the immune system (the body's natural defences) and is used to treat the following conditions:

- moderate to severe plaque psoriasis (a disease causing red, scaly patches on the skin) in adults and children above 6 years old who need treatment with a systemic medicine (a medicine given by mouth or by injection);
- psoriatic arthritis (inflammation of the joints associated with psoriasis) in adults when disease-modifying anti-rheumatic drugs (DMARDs) do not work well enough;
- axial spondyloarthritis (inflammation of the spine causing back pain) in adults, including ankylosing spondylitis when X-ray shows the disease, and non-radiographic axial spondyloarthritis when there are clear signs of inflammation but X-ray does not show disease. It is used when conventional treatments do not work well enough;
- two types of juvenile idiopathic arthritis (a form of arthritis in children), enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA), in patients from 6 years of age when conventional therapy does not work well enough or is not tolerated. Cosentyx can be used on its own or in combination with methotrexate (a DMARD medicine);
- hidradenitis suppurativa (acne inversa), a long-term skin disease that causes lumps, abscesses (collections of pus) and scarring on the skin, in adults. It is used to treat moderate-to-severe, active disease when conventional systemic treatments do not work well enough.

Cosentyx contains the active substance secukinumab.

How is Cosentyx used?

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

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Cosentyx is given by injection under the skin every week for 5 weeks and then once a month as maintenance treatment. For hidradenitis suppurativa, Cosentyx can also be given every two weeks for maintenance treatment..

The condition being treated usually improves within 16 weeks of treatment. The doctor may decide to stop treatment if there is no improvement after 16 weeks.

Patients (or their carers) can give the injection if they have been trained to do so. For more information about using Cosentyx, see the package leaflet or contact your doctor or pharmacist.

How does Cosentyx work?

The active substance in Cosentyx, secukinumab, is a monoclonal antibody, a type of protein, designed to attach to a protein called interleukin-17A. Interleukin-17A is involved in inflammation and other immune system processes that cause psoriasis, psoriatic arthritis, axial spondyloarthritis and hidradenitis suppurativa. By attaching to interleukin-17A, secukinumab blocks its action and so reduces the activity of the immune system and symptoms of the disease.

What benefits of Cosentyx have been shown in studies?

Plaque psoriasis

Studies showed that Cosentyx is effective in treating psoriasis, psoriatic arthritis and axial spondyloarthritis, 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 adults, 79% of those on Cosentyx had 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 treated with etanercept and 4% of those receiving 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 severe psoriasis in 162 children from 6 years of age, around 80% of children given Cosentyx achieved a 75% reduction in their PASI scores and around 70% had skin that was clear or almost clear of psoriasis after 12 weeks. This compares with 66% and 36%, respectively, for patients treated with etanercept and 15% and 6% for patients treated with placebo.

Psoriatic arthritis

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.

Ankylosing spondylitis

In a study of 219 adults with ankylosing spondylitis, 61% of patients given the approved dose of Cosentyx had a 20% reduction in ASAS scores (back pain, morning stiffness and other symptoms) after 16 weeks, compared with 28% of patients on placebo. In another study involving 555 adults with non-radiographic axial spondyloarthritis, 41% of patients given the approved dose of Cosentyx had a 40% reduction in ASAS scores after 16 weeks, compared with 29% of patients on placebo.

Juvenile idiopathic arthritis

In a study involving 75 children between 2 and 17 years of age with active ERA or JPsA, fewer patients treated with Cosentyx had a flare-up of their condition compared with those given placebo (10 versus

21). As the study included only a few children younger than six years of age, data from this age group were inconclusive and Cosentyx is therefore to be used from the age of six.

Hidradenitis suppurativa

In 2 studies involving 1,084 adults with moderate to severe hidradenitis suppurativa, 44% of patients who were given Cosentyx achieved at least 50% reduction in abscesses and nodules after 16 weeks, without any increase in the number of abscesses or fistulas (abnormal passageway). The proportion of patients given placebo who achieved this response was 32%.

What are the risks associated with Cosentyx?

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

The most common side effects with Cosentyx (which may affect more than 1 in 10 people) include upper respiratory tract infections (nose and throat infections) with inflammation of the nose and throat (nasopharyngitis) and blocked or runny nose (rhinitis).

Because Cosentyx can increase the risk of infection, it must not be given to patients with serious infections such as tuberculosis.

Why is Cosentyx authorised in the EU?

In studies, Cosentyx was of substantial clinical benefit in patients with psoriasis, psoriatic arthritis, axial spondyloarthritis, enthesitis-related arthritis and juvenile psoriatic arthritis. Cosentyx has been shown to provide a relevant treatment effect in adult patients with moderate to severe hidradenitis suppurativa, a disease that has few systemic treatment options. Information regarding long-term use in patients with hidradenitis suppurativa is limited and studies are ongoing to evaluate this. The safety profile was considered reassuring, with the main concern related to mild infections. The European Medicines Agency therefore decided that Cosentyx'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 Cosentyx?

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

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

Other information about Cosentyx

Cosentyx received a marketing authorisation valid throughout the EU on 15 January 2015.

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

This overview was last updated in 05-2023.