

What is Cosentyx® (secukinumab)?

Cosentyx is the first of a new class of medicines called interleukin-17A (IL-17A) inhibitors to be approved for the treatment of moderate-to-severe plaque psoriasis, active psoriatic arthritis (PsA) and active ankylosing spondylitis (AS).

Cosentyx is a fully human monoclonal antibody that selectively blocks circulating Interleukin-17A (IL-17A)¹.

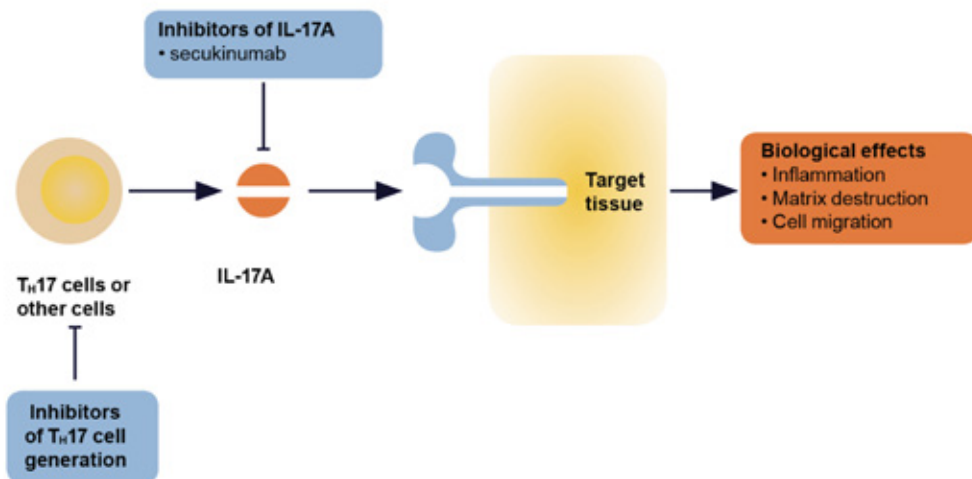
What is IL-17A?

IL-17A is one of many proteins in the body called cytokines that help protect the body against infections². Cytokines usually work by signalling to infection-fighting cells that they need to mount an immune response once foreign invaders, such as bacteria or other disease causing germs, have been detected².

If the body produces too much of a particular cytokine, it can trigger problems, including pain and tissue damage. Cosentyx targets IL-17A, the key cytokine involved in the development of a number of immune-mediated diseases such as psoriasis, PsA and AS³. Higher concentrations of IL-17A are found near the skin of people with psoriasis, and in the joints and spine in people suffering from PsA and AS^{4,5}. IL-17A is, therefore, considered an optimal target for therapies in these disease areas^{2,3}.

How does Cosentyx work?

Cosentyx selectively identifies and binds to circulating IL-17A, preventing it from binding with cell receptors. This action disables IL-17A activity and its ability to cause inflammation.



In psoriasis, reduction in inflammation decreases the associated symptoms such as redness, itching and swelling. It also slows the characteristic fast growth of new skin cells and buildup of cells on the skin's surface, known as plaques⁶. In PsA and AS, the inhibition of IL-17A leads to less tender and swollen joints and better function^{7,8,9}.

Why is there a need for new treatment?

Psoriasis doesn't only affect the skin. It is a systemic, chronic (long-lasting), and distressing disease that can negatively affect all aspects of daily life¹⁰. Psoriasis has been shown to regularly limit people's ability to undertake daily, work and social activities, and

also impacts their mental and emotional health¹⁰. Psoriasis is also associated with other serious health conditions, such as depression, diabetes and heart disease¹¹. PsA and AS, if not treated effectively, can lead to irreversible damage to the joints and spine, causing life-long pain and disability⁴. PsA and AS are also associated with significant reduced life expectancy and represent a major economic burden for society¹².

New medicines with an alternative way of working are needed urgently as many patients do not tolerate or achieve an adequate response from current treatments such as anti-tumor necrosis factor (anti-TNF) therapies, and in PsA and AS, disease-modifying anti-rheumatic drugs (DMARDs) and non-steroidal anti-inflammatories.

- 45% of PsA patients are dissatisfied with their treatments³
- 40% of AS patients do not respond sufficiently to anti-TNF therapies⁴
- 52% of patients with mild, moderate and severe psoriasis are dissatisfied with their disease management³

Prevalence¹⁵⁻²²

	Psoriasis	PsA	AS
Global	Up to 3% / >125 million	71 million	13 million
EU	0.8% ~ 3.7 million Europeans	3.1 million	1.78 million
USA	~ 7.5 million people	~3.2 million	Up to 0.5% of population ~500,000 people

Cosentyx is currently authorized for the treatment of^{23,*}

- **Psoriasis:** Adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy
- **PsA:** Adults with active PsA who have not responded adequately to previous DMARDs
- **AS:** Adults with active AS who have responded inadequately to conventional therapy

Where is Cosentyx currently licensed for use?²⁴

Psoriasis: Cosentyx is approved in 79 countries for the treatment of moderate-to-severe plaque psoriasis which includes the European Union countries, Japan, Switzerland, Australia, the US and Canada.

- In Europe, Cosentyx is approved as a first-line systemic treatment of moderate-to-severe plaque psoriasis in adult patients
- In the US, Cosentyx is approved as a treatment for moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy (light therapy)

PsA and AS: Cosentyx is the first IL-17A inhibitor approved in more than 70 countries for the treatment of active AS and PsA, which includes the European Union countries and the US. For AS, this is the first new treatment advance in 16 years since the development of the first anti-tumor necrosis factor (anti-TNF) therapy.

In addition, Cosentyx is approved in Ecuador, Bangladesh, South Korea and the Philippines for PsA and AS, and for the treatment of PsA and pustular psoriasis in Japan.

To date, more than 100,000 patients worldwide have been prescribed Cosentyx in the post-marketing setting across all indications and over 18,000 patients with psoriasis have already been treated in the post-marketing setting²⁴. In addition, 2017 marks 10 years since the first patient, first visit in a clinical trial with Cosentyx. Cosentyx has demonstrated a favourable safety profile across multiple indications²³. The risk-benefit assessment has not changed in the post-market setting²⁴.

Cosentyx in clinical trials

To date, Cosentyx data have achieved major publications in the New England Journal of Medicine (NEJM) and The Lancet:

- **Psoriasis:** ERASURE data published in NEJM showed that 81.6% of patients achieved 75% skin clearance (PASI 75 response) at Week 12 with Cosentyx 300 mg and 71.6% with Cosentyx 150 mg²⁵. Cosentyx reached all secondary end points with 59% of patients on Cosentyx 300 mg and 39% of patients on Cosentyx 150 mg reaching PASI 90 response at Week 12 versus 1.2% on placebo.

Data from the Phase III A2304E1 study, presented at the 26th European Academy of Dermatology and Venerology (EADV) 2017 Congress, showed that from Year 1 (Week 52) to the end of Year 5 (Week 260), PASI 75/90/100 response rates remained consistent for Cosentyx²⁶. Specifically, PASI 75 and PASI 90 response rates were achieved by 89% and 69% of psoriasis patients respectively, at Year 1, and were maintained out to Year 5 (89% and 66%, respectively)²⁶.

- **PsA:** Study results, from FUTURE 1 and FUTURE 2, were published in NEJM⁸ and The Lancet⁷. After two years of treatment, 67% of patients treated with Cosentyx 150 mg achieved an ACR 20 response (American College of Rheumatology response criteria) in FUTURE 1. In FUTURE 2, improvements seen with Cosentyx 150 mg and 300 mg were sustained over one year of treatment in 64% of patients as measured by ACR 20. In FUTURE 1 at two years, 84% of patients showed no radiographic progression in joint damage.

FUTURE 5 is the largest randomized controlled trial of a biologic conducted to date in PsA, with nearly 1,000 patients studied. Results demonstrate that as many as 88% of patients taking Cosentyx 300 mg and 79% of patients taking Cosentyx 150 mg had no worsening of joint damage at Week 24, compared to 73% on placebo²⁷.

- **AS:** Two pivotal studies, MEASURE 1 and MEASURE 2, published in NEJM demonstrated significant clinical improvements with Cosentyx versus placebo in the signs and symptoms of active AS⁹. In MEASURE 1 the Assessment of Spondyloarthritis International Society response criteria (ASAS20) response rates at week 16 were 60% and 61% for Cosentyx 75 mg and 150 mg respectively. In MEASURE 2, the rates were 41% and 61% for 75 mg and 150 mg. In MEASURE 2 improvements in the signs and symptoms of AS were sustained through 52 weeks of treatment; 74% of patients achieved ASAS20 response at one year⁹. A sub-study showed up to 80% of AS patients treated with Cosentyx had no radiographic progression in the spine or joints over two years¹.

The new long-term MEASURE 1 data shows that nearly 80% of patients demonstrated no radiographic progression over four years of treatment^{*28}. The potential slowing down of the structural progression of AS in the spine was paired with sustained results on patient-reported pain measures, with over 75% preserving an ASAS 20 response at four years²⁸.


The ERASURE, FUTURE 1, 2 and 5 and MEASURE 1 and 2 studies are multi-center, randomized, placebo-controlled studies designed to evaluate the efficacy and safety of Cosentyx in psoriasis, AS and PsA^{7,8,9}. Additional follow-up of patients from these trials is still ongoing^{7,8,9}.

Novartis continues to investigate Cosentyx for its potential role in preventing radiographic progression of spinal and joint structural damage in AS and PsA patients respectively, as shown by x-ray.

*Based on score of <2, indicated by the modified Stoke Ankylosing Spondylitis Spinal Score (mSASSS) X-ray assessment measure²⁸

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* Please refer to guidelines and full prescribing information in your country for further information