Ankylosing spondylitis and COSENTYX®

COSENTYX® (secukinumab) is indicated for the treatment of:[1]

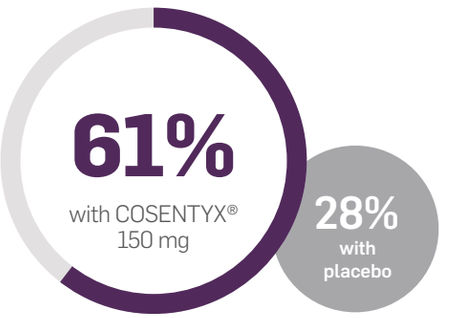
- Adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy

Pr Cosentyx®
secukinumab

For the ankylosing spondylitis you may not see

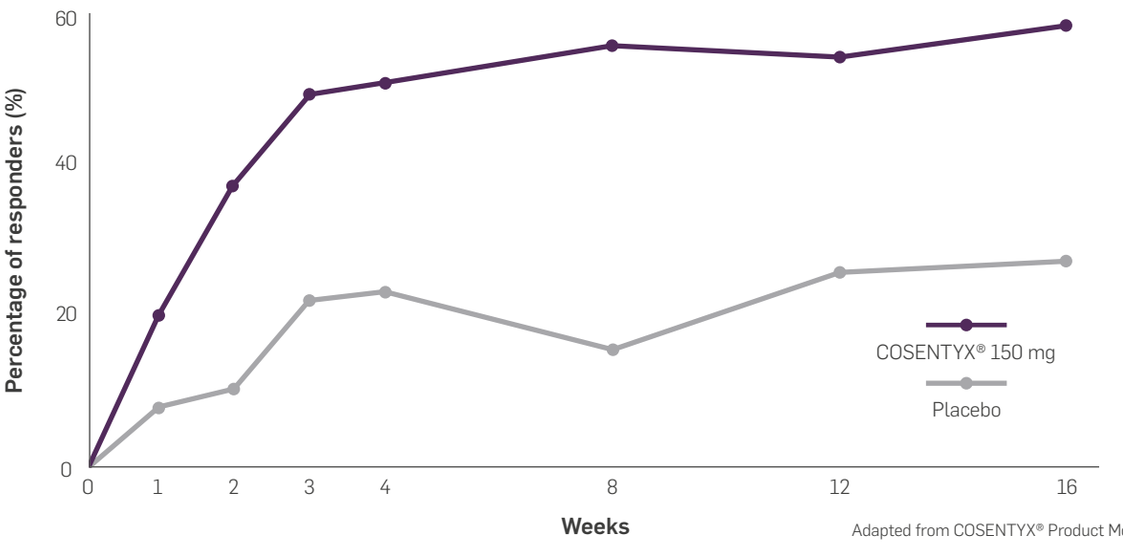
In MEASURE 2, a study in patients with active ankylosing spondylitis (AS):*

At Week 16
ASAS 20



61% of COSENTYX® 150 mg patients achieved ASAS 20 at Week 16 (vs. 28% placebo; p=0.0001; primary endpoint)[1]*

Percentage of COSENTYX® 150 mg patients achieving ASAS 20 response through Week 16 vs. placebo*



Adapted from COSENTYX® Product Monograph.

The ASAS 20 is a composite measure defined as:[1]

- 20% improvement in Assessment of SpondyloArthritis International Society criteria. The main components of the ASAS 20 criteria are the following:
  - Patient global assessment
  - Total spinal pain
  - BASFI
  - Inflammation (as measured by the mean of two patient-reported stiffness self-assessments in BASDAI)

ASAS=Assessment of SpondyloArthritis International Society; BASDAI=Bath Ankylosing Spondylitis Disease Activity Index; BASFI=Bath Ankylosing Spondylitis Functional Index.

* MEASURE 2 was a randomized, multicentre, double-blind, placebo-controlled phase 3 trial evaluating the safety and efficacy of COSENTYX® in patients with active ankylosing spondylitis (BASDAI ≥4) despite non-steroidal anti-inflammatory drug (NSAID), corticosteroid or disease-modifying anti-rheumatic drug (DMARD) therapy. Patients were randomized in a 1:1:1 ratio to receive COSENTYX® at a dose of 75 mg (n=73) or 150 mg (n=72), or placebo (n=74) at Weeks 0, 1, 2 and 3, followed by the same dose every month. Primary endpoint was percentage of patients achieving at least a 20% improvement in the Assessment of SpondyloArthritis International Society (ASAS 20) criteria at Week 16. Select secondary endpoint was ASQoL. Patients receiving placebo were re-randomized 1:1 to receive COSENTYX® (either 75 mg or 150 mg every 4 weeks) at Week 16. 11.9% and 14.2% of patients in the trial used concomitant MTX or sulfasalazine, respectively. In ankylosing spondylitis, COSENTYX® is not indicated for use in combination with MTX or sulfasalazine. [1]

Demonstrated efficacy results in AS quality of life on COSENTYX® as measured by the ASQoL*

-4.00

Mean change of -4.00 from baseline at Week 16 observed in patients on COSENTYX® 150 mg (n=72) vs. -1.37 with placebo (n=74); $p<0.01$; secondary endpoint.[1,2*]

The ASQoL includes measures such as:[3]

- Sleep
- Mood
- Motivation
- Coping
- Activities of daily living
- Independence
- Social life
- Relationships

ASQoL=Ankylosing Spondylitis Quality of Life.

Important safety information

Indication and clinical use:

COSENTYX® (secukinumab) is indicated for the treatment of:

- Moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy
- Severe plaque psoriasis in pediatric patients 12 to less than 18 years of age who are candidates for systemic therapy or phototherapy and have a body weight ≥50 kg
- Adult patients with active psoriatic arthritis when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. COSENTYX® can be used alone or in combination with methotrexate
- Adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy

Geriatric patients ≥65 years of age: although limited in patient number, no differences in safety or efficacy were observed between older and younger patients.

Pediatrics <18 years of age: safety and effectiveness in pediatric patients with severe plaque psoriasis below the age of 12 years have not been established. Safety and effectiveness in pediatric patients with the principal diagnosis of psoriatic arthritis or ankylosing spondylitis below the age of 18 years have not been established.

Contraindications:

- Severe hypersensitivity to the active substance or any of its components

Relevant warnings and precautions:

- Infections: could potentially increase risk of infections; caution in patients with a chronic infection or history of recurrent infections; patients should be evaluated for tuberculosis prior to initiation of treatment with COSENTYX®
- Caution in patients with active inflammatory bowel disease
- Caution in latex-sensitive patients: natural rubber latex derivatives in the removable cap of the prefilled syringe/COSENTYX® SensoReady® pen
- Consider completion of all age-appropriate immunizations according to current guidelines prior to treatment; should not be used with live vaccinations; can be used with those that are inactivated or non-live
- Hypersensitivity reactions: rare cases of anaphylaxis and cases of urticaria occurred in COSENTYX®-treated patients in clinical trials
- Pregnancy: should only be used if the potential benefit justifies the potential risk to the fetus
- Nursing women: caution should be exercised

For more information:

Consult the Product Monograph at www.novartis.ca/CosentyxMonograph for important information relating to adverse reactions, drug interactions and dosing information which has not been discussed in this piece. The Product Monograph is also available by calling 1-800-363-8883.

References: 1. COSENTYX Product Monograph. Novartis Pharmaceuticals Canada Inc. January 20, 2021. **2.** Baeten D, Sieper J, Braun J, *et al.* Secukinumab, an interleukin-17A inhibitor, in ankylosing spondylitis. *N Engl J Med.* 2015:373:2534-2548. doi: 10.1056/NEJMoa1505066. **3.** Zochling J. Measures of symptoms and disease status in ankylosing spondylitis: Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), and Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S). *Arthritis Care Res.* 2011 Nov;63 Suppl 11:S47-58. doi: 10.1002/acr.20575

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