Psoriatic arthritis and COSENTYX®

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

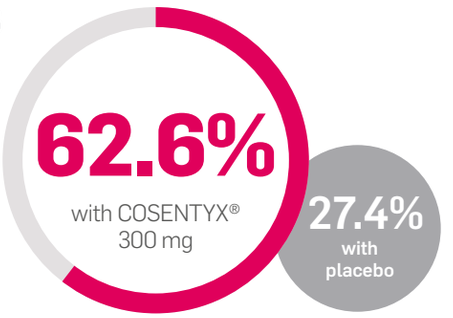
- Adult patients with active psoriatic arthritis when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. COSENTYX® can be used alone or in combination with methotrexate

Pr Cosentyx® secukinumab

For the psoriatic arthritis you may not see

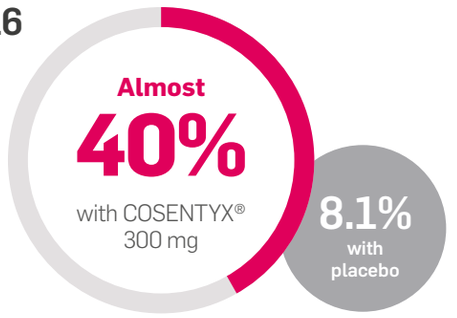
In FUTURE 5, a study in patients with active psoriatic arthritis:*

At Week 16
ACR 20



62.6% of COSENTYX® 300 mg patients achieved ACR 20 at Week 16 and 55.5% of COSENTYX® 150 mg patients achieved ACR 20 at Week 16 (vs. 27.4% placebo; $p<0.0001$; primary endpoint)[1]*

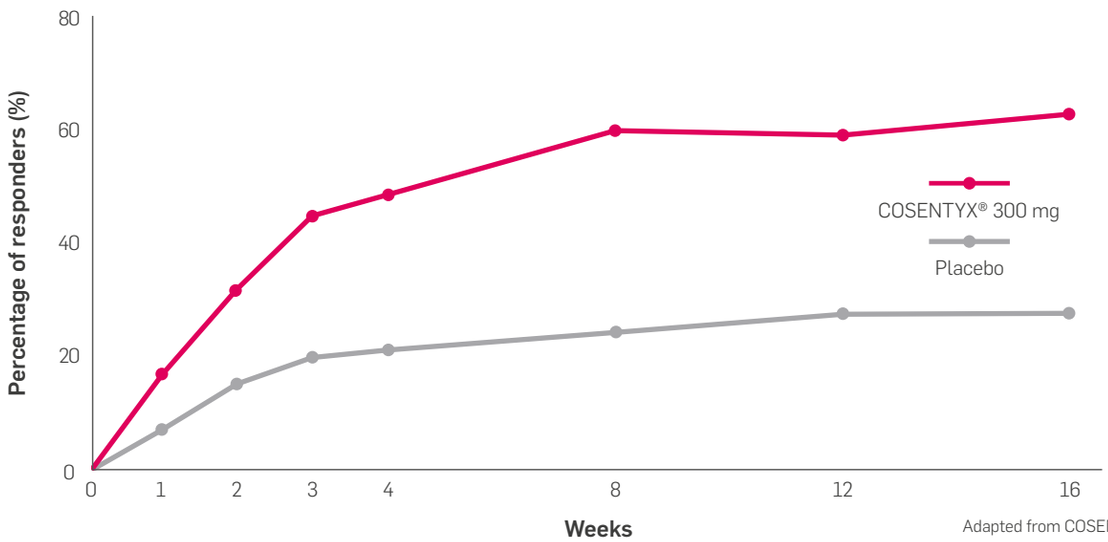
At Week 16
ACR 50



39.6% of COSENTYX® 300 mg patients achieved ACR 50 at Week 16 and 35.9% of COSENTYX® 150 mg patients achieved ACR 50 at Week 16 (vs. 8.1% placebo; difference 31.5%; 95% CI: 24.4%, 38.6%; secondary endpoint)[1]*

Maintained to **Week 24**

Percentage of COSENTYX® 300 mg patients achieving ACR 20 response through Week 16 vs. placebo*



Adapted from COSENTYX® Product Monograph.

The ACR 20 is a composite measure defined as:[2]

- 20% improvement in the number of tender and number of swollen joints, **and**
- 20% improvement in three of the following five criteria:
  - Patient global assessment
  - Physician global assessment
  - Functional ability measure (most often Health Assessment Questionnaire [HAQ])
  - Visual analog pain scale
  - Erythrocyte sedimentation rate or C-reactive protein (CRP)

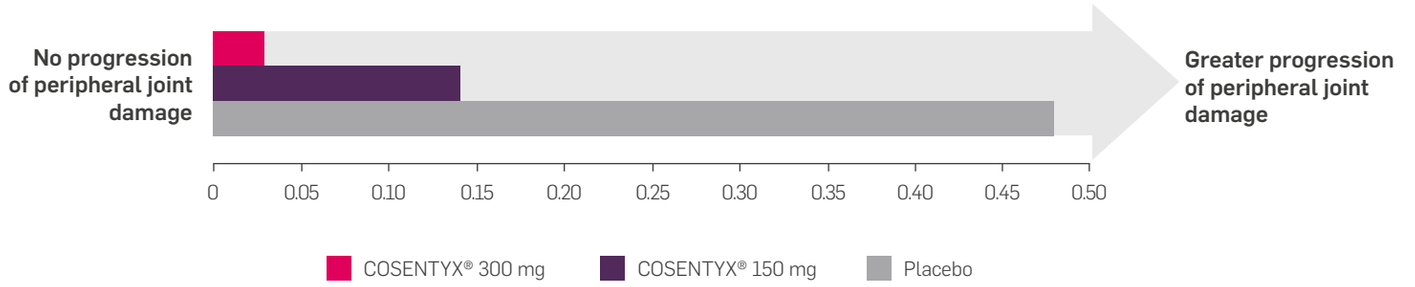
The ACR 50 is the same instrument, with improvement levels defined as 50% versus 20% for ACR 20.[2]

ACR=American College of Rheumatology.

* FUTURE 5 was a randomized, multicentre, double-blind, placebo-controlled phase 3 trial evaluating the safety and efficacy of COSENTYX® in patients with active psoriatic arthritis (≥3 swollen and ≥3 tender joints) despite non-steroidal anti-inflammatory drug (NSAID), corticosteroid or disease-modifying anti-rheumatic drug (DMARD) therapy. Patients were randomized in a 2:2:2:3 ratio to receive COSENTYX® at a dose of 150 mg without loading dose (n=222) (dosing arm is an off-label dose not authorized for use), 150 mg with loading dose (n=220) or 300 mg with loading dose (n=222), or placebo (n=332) 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 American College of Rheumatology (ACR 20) criteria at Week 16. Select secondary endpoints were ACR 50, mTSS and HAQ-DI. Patients receiving placebo were re-randomized to receive COSENTYX® (either 150 mg or 300 mg every 4 weeks) at Week 16 or Week 24 based on responder status (<20% improvement from baseline in both tender and swollen joint counts). 50.1% of patients in the trial had concomitant MTX treatment.[1,3]

COSENTYX® 150 mg and 300 mg treatment inhibited the rate of progression of peripheral joint damage compared with placebo treatment as measured by the change from baseline in mTSS at Week 24 (secondary endpoint)[1]*

Patients on COSENTYX® 300 mg saw a mTSS mean change of 0.03 from baseline, -0.45 vs. placebo (95% CI: -0.79, -0.12). Patients on COSENTYX® 150 mg saw a mTSS mean change of 0.14 from baseline, -0.34 vs. placebo (95% CI: -0.68, 0.00).[1]*



Demonstrated efficacy results as measured by the Health Assessment Questionnaire-Disability Index*

-0.55

On a scale from 0–3 with higher numbers indicating worse function, -0.55 mean change from baseline at Week 16 observed in patients on COSENTYX® 300 mg (n=222) and -0.44 mean change from baseline at Week 16 observed in patients on COSENTYX® 150 mg (n=220), vs. -0.21 with placebo (n=332); $p<0.05$; secondary endpoint.[1,3]*

The HAQ-DI includes measures such as:[1]

- Dressing/grooming
- Arising
- Eating
- Walking
- Maintaining hygiene
- Reaching
- Gripping
- Maintaining daily activity

In psoriatic arthritis, the recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, the recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing.

If a patient is an anti-TNF-alpha inadequate responder (IR) or continues to have active psoriatic arthritis, consider using the 300 mg dose.

Please see Product Monograph for complete dosing and administration information.

mTSS=Modified Total Sharp Score.

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.** American College of Rheumatology Committee to Reevaluate Improvement Criteria. A proposed revision to the ACR20: the hybrid measure of American College of Rheumatology response. *Arthritis Rheum.* 2007;57(2):193-202. **3.** Mease P, Heijde D, Landewé R, *et al.* Secukinumab improves active psoriatic arthritis symptoms and inhibits radiographic progression: primary results from the randomized, double-blind phase III FUTURE 5 study. *Ann Rheum Dis.* 2018;77:890-897. doi: 10.1136/annrheumdis-2017-212687.

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