Difficult-to-treat psoriasis and COSENTYX®

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

- 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.

Pr Cosentyx® secukinumab

For the difficult-to-treat forms of psoriasis you see

In TRANSFIGURE, a **132-week study** in patients with chronic moderate to severe plaque psoriasis with nail involvement*:

At Week 16

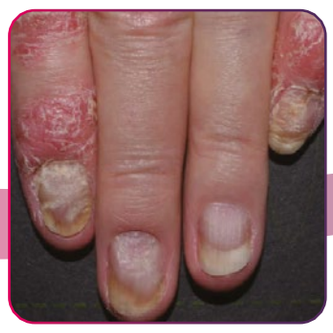
Nail Psoriasis Severity Index (NAPSI)

>45%

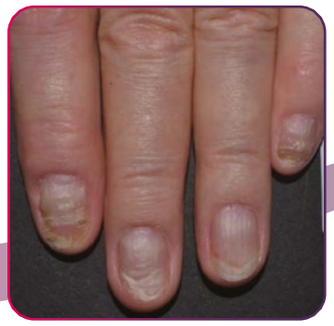
improvement shown in NAPSI with COSENTYX®

11.7% with placebo

Mean improvement of 46.1% on the NAPSI in patients on COSENTYX® at Week 16 (adjusted mean from baseline) vs. 11.7% on placebo (difference in adjusted means -34.4% [95% CI: -45.2, -23.5]; $p<0.0001$).[1]*



Baseline†



Week 16†

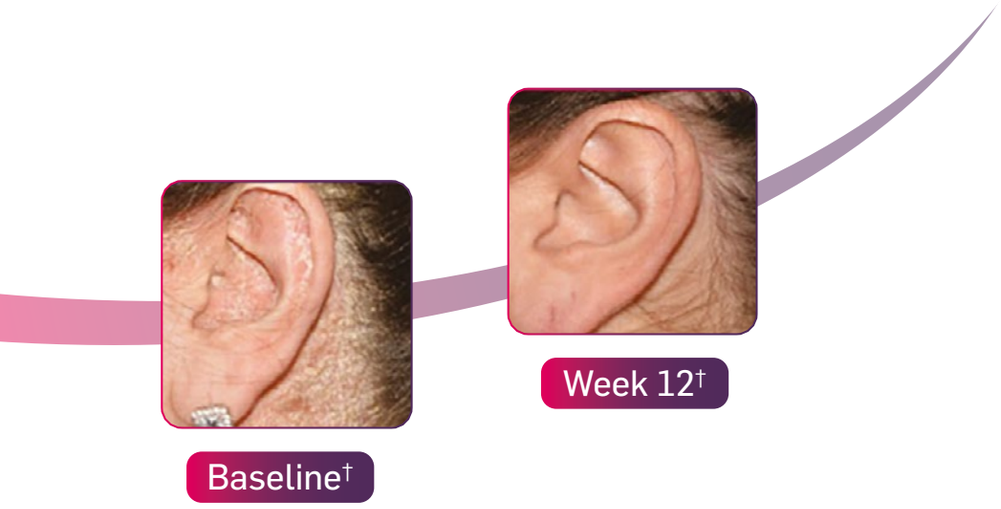
Patients were adults with chronic moderate to severe plaque-type psoriasis for at least 6 months prior to randomization including significant nail involvement defined by fingernail NAPSI ≥16, number of fingernails involved ≥4, a PASI score ≥12 and BSA ≥10%.

CI=confidence interval; NAPSI=Nail Psoriasis Severity Index; PASI=Psoriasis Area and Severity Index.

* TRANSFIGURE was a randomized, double-blind, placebo-controlled, parallel-group, multicentre phase 3 study. Patients had to be candidates for systemic therapy defined as having psoriasis considered inadequately controlled by topical treatment and/or phototherapy and/or previous systemic therapy. Patients were randomized to receive COSENTYX® 300 mg (n=66) or 150 mg (n=67), or placebo (n=65). The primary endpoint was percentage change from baseline at Week 16 in NAPSI score. At Week 16, all placebo patients were re-randomized to COSENTYX® 150 mg or 300 mg and the study continued to 132 weeks.[1]

† Individual results may vary. May not be representative of the general population.

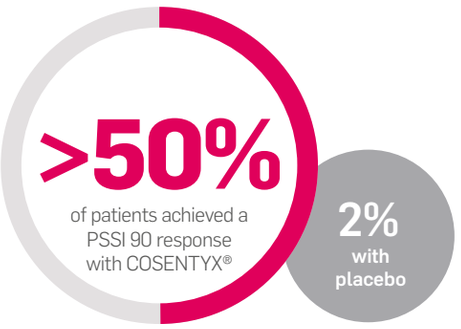
In SCALP, a **24-week study** in patients with moderate to severe scalp psoriasis*:



Patients were adults with moderate to severe scalp psoriasis, defined as having a Psoriasis Scalp Severity Index (PSSI) score of ≥12, an Investigator's Global Assessment (IGA) modified version 2011 scalp-only score of ≥3, and ≥30% of the scalp affected. In this study, 62% of patients had ≥50% of scalp surface area affected.

At Week 12

Psoriasis Scalp Severity Index (PSSI) 90



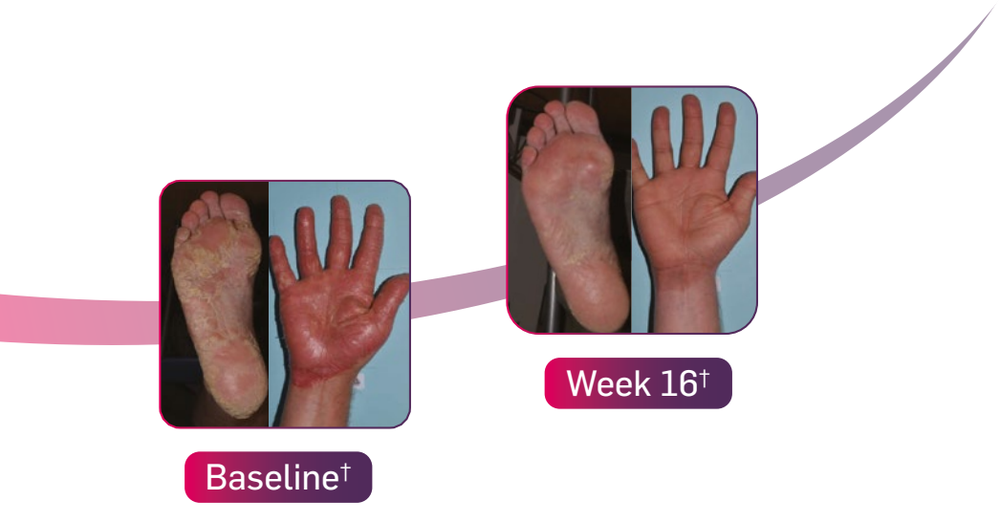
52.9% of patients on COSENTYX® achieved a PSSI 90 response at Week 12 vs. 2.0% on placebo ($p<0.001$) as well as a clear or almost clear response (IGA scalp-only score of 0 or 1) (56.9% vs. 5.9%; $p<0.001$; secondary endpoint).[1*]

IGA=Investigator's Global Assessment; PSSI=Psoriasis Scalp Severity Index.

* SCALP was a randomized, double-blind, placebo-controlled, parallel-group, multicentre study. Patients with moderate to severe scalp psoriasis (with or without plaque psoriasis elsewhere on the body) of ≥6 months' duration that was inadequately controlled by topical treatments, phototherapy or systemic therapies were eligible for this trial. Patients were randomized to receive COSENTYX® 300 mg (n=51) or placebo (n=51). The primary endpoint was proportion of patients in each group achieving a PSSI 90 response at Week 12. A key secondary endpoint was proportion of patients in each group achieving an IGA mod 2011 response (for the scalp only) of 0 (clear) or 1 (almost clear) at Week 12. At Week 12, patients treated with placebo who did not achieve a PSSI 90 response were switched to COSENTYX®; all other patients remained in the same groups. The study continued to 24 weeks.[1,2]

† Individual results may vary. May not be representative of the general population.

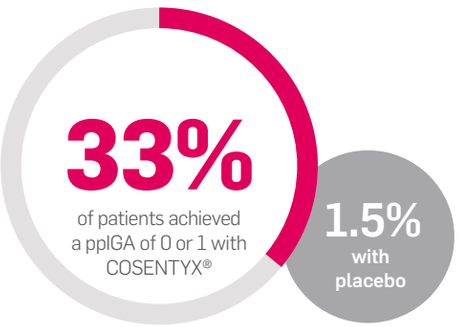
In GESTURE, a **132-week study** in patients with chronic moderate to severe plaque psoriasis with palmoplantar involvement*:



Patients were adults with chronic moderate to severe plaque-type psoriasis for at least 6 months including at baseline significant involvement of palms and soles as defined by a Palmoplantar Investigator's Global Assessment (ppIGA) score of ≥3 (on a 5-point scale) and at least 1 extra psoriasis plaque on the skin. The ppIGA scale was based on the IGA modified version 2011 specifically applied to the palms and soles; the ppIGA is a non-validated tool for the measurement of palmoplantar psoriasis severity.

At Week 16

Palmoplantar Investigator's Global Assessment (ppIGA)



33.3% of patients on COSENTYX® achieved a ppIGA of 0 or 1 at Week 16 vs. 1.5% on placebo (p<0.0001; primary endpoint).[1*]

ppIGA=Palmoplantar Investigator's Global Assessment.

* GESTURE was a randomized, double-blind, placebo-controlled, parallel-group, multicentre phase 3 study. Patients were candidates for systemic therapy defined as having psoriasis considered inadequately controlled by topical treatment (including super-potent topical corticosteroid) and/or phototherapy and/or previous systemic therapy. Patients were randomized to receive COSENTYX® 300 mg (n=69), COSENTYX® 150 mg (n=68) or placebo (n=68). The primary endpoint was ppIGA score of 0 (clear) or 1 (almost clear/minimal) response at Week 16 (to be considered a ppIGA responder at Week 16, a patient had a ppIGA score of 0 or 1 at the Week 16 visit and a reduction of at least 2 points on the ppIGA scale from baseline). At Week 16 and at Week 80, patients treated with placebo who were not ppIGA 0 or 1 responders were re-randomized to receive COSENTYX® 150 mg or 300 mg. Patients in the COSENTYX® treatment groups remained in the same groups. The study continued to 132 weeks.[1]

† Individual results may vary. May not be representative of the general population.

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.** Bagel J, Duffin KC, Moore A, *et al.* The effect of secukinumab on moderate-to-severe scalp psoriasis: results of a 24-week, randomized, double-blind, placebo-controlled phase 3b study. *J Am Acad Dermatol.* 2017;4:667-74. doi: 10.1016/j.jaad.2017.05.033.

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