1,000,000 patients treated globally and counting, across indications[8]

Cosentyx® secukinumab

Proven efficacy in skin and joints with Cosentyx® (secukinumab)[1–7]

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report, or alternatively email medinfo.uk@novartis.com or call 01276 698370.

Indications:
Treatment of: **moderate to severe plaque psoriasis** in adults, adolescents and children from the age of 6 years who are candidates for systemic therapy; **active psoriatic arthritis** in adults (alone or in combination with methotrexate) who have responded inadequately to disease-modifying anti-rheumatic drug therapy; **active ankylosing spondylitis** in adults who have responded inadequately to conventional therapy; **active non-radiographic axial spondyloarthritis** with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; **active enthesitis-related arthritis and juvenile psoriatic arthritis** in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; **active moderate to severe hidradenitis suppurativa (acne inversa)** in adults with an inadequate response to conventional systemic HS therapy.[9]

Please refer to the Cosentyx Summary of Product Characteristics (SmPC) for further information about the clinical indications.[9]

Cosentyx is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which Cosentyx is indicated. Please refer to the Cosentyx SmPC for dosing in special populations.[9]

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NOVARTIS

How could Cosentyx benefit your eligible patients?

Symptom relief from all six key manifestations of PsA, key hallmarks of axSpA and skin clearance in PsO were observed with Cosentyx

The six key manifestations of PsA are joints, axial, skin, enthesitis, dactylitis, and nails; key hallmarks of axSpA are morning stiffness, spinal pain, fatigue, and nocturnal back pain.[10,11]

Skin clearance in PsO

44% of patients achieved PASI100 (secondary endpoint, observed data; N=41) at **Week 12**[*1]

55% of patients achieved PASI100 (secondary endpoint, observed data; N=41) at **Year 1**[*1]

Co-primary endpoints of PASI75 and IGA mod 2011 0/1 response at Week 12 were met for Cosentyx 300 mg vs placebo (95% vs 10% and 76% vs 8% respectively, p<0.001).[1]

Nail improvement in PsO

45% improvement in NAPSI (primary endpoint; N=66) from baseline achieved at **Week 16** vs 11% placebo; p<0.0001[†2]

73% improvement in NAPSI (observed data; N=66) sustained at **Year 2.5**[†3]

Joint relief in PsA

46% of patients achieved ACR50 (secondary endpoint; N=83) at **Week 12** vs 8% placebo; p<0.0001[‡4]

68% of patients achieved ACR50 (observed data; N=83) at **Year 1**[‡5]

Primary endpoint of mean change from baseline to Week 12 in GLOESS for Cosentyx vs placebo was met (−9 vs −6, p=0.004).[1]

Axial joint relief in AS

56% of patients achieved BASDAI50 (observed data ; N=122) at **Year 1**[§6]

63% of patients achieved BASDAI50 (observed data ; N=122) at **Year 5**[§6]

The primary endpoint of ASAS20 response rate at Week 16 for Cosentyx 150 mg vs placebo was met (61% vs 29%, p<0.001).[11,12]

Dactylitis resolution in PsA

88% of patients achieved complete resolution (observed data) at **Year 5**[¶7]

Primary endpoint of ACR20 response at Week 24 for Cosentyx 300 mg and 150 mg vs placebo was met (54%, 51% vs 15%, p<0.001).[13]

Enthesitis resolution in PsA

77% of patients achieved complete resolution (observed data) at **Year 5**[¶7]

Primary endpoint of ACR20 response at Week 24 for Cosentyx 300 mg and 150 mg vs placebo was met (54%, 51% vs 15%, p<0.001).[13]

Cosentyx has a consistent safety profile with over 8 years of real-world evidence across licensed indications.[9]

The most frequently reported adverse reactions are upper respiratory tract infections (17.1%) (most frequently nasopharyngitis, rhinitis).[9]

Please refer to the Cosentyx SmPC for full prescribing and administration information, including special populations.

FAST and LASTING joint symptom relief and skin clearance[1–7]

FAST and LASTING refers to the data at 12/16 weeks (FAST) or ≥52 weeks (LASTING) presented in this document.

[§]Cosentyx IV is off-label. Cosentyx should be administered subcutaneously: please refer to the SmPC for full information.

[*]MATURE (N=122) was a 52-week, multicentre, double-blind, randomised, placebo-controlled, Phase III trial in patients with PsO. Eligible patients were randomised to Cosentyx 300 mg or placebo. The co-primary endpoints were PASI75 and IGA mod 2011 0/1 responses at Week 12. Other endpoints included total skin clearance PASI100. The study met the co-primary endpoints. At Week 12, PASI100 was greater with 300 mg Cosentyx AI treatment (43.9%, p<0.0001) than with placebo (0%). The response rates were sustained up to Week 52 with PASI100 reported in 55.4% of patients.[1]

[†]TRANSFIGURE (N=198) was a double-blind, randomised, placebo-controlled, Phase III study of the safety and efficacy of Cosentyx in patients with moderate-to-severe nail psoriasis. Patients were randomised to the three study groups: Cosentyx 300 mg (N=66), Cosentyx 150 mg (N=67) and placebo (N=65). The primary objective was to demonstrate the superiority of Cosentyx over placebo, as assessed by the percentage change in total fingernail NAPSI score from baseline to Week 16. The primary objective was met: at Week 16, the mean percentage NAPSI changes were −45.3% and −10.8%, for Cosentyx 300 mg and placebo, respectively, p<0.001).[2] The effect was sustained over 2.5 years with a mean NAPSI improvement of −73.3% for Cosentyx 300 mg.[3]

[‡]ULTIMATE (N=166) was a multicentre, randomised, double-blind, placebo-controlled, 52-week, Phase III study, in patients with PsA. Patients were randomly assigned to receive either weekly subcutaneous Cosentyx (300 or 150 mg according to the severity of psoriasis) or placebo followed by 4-weekly dosing thereafter. The primary outcome was the mean change in the ultrasound Global EULAR and OMERACT Synovitis Score (GLOESS) from baseline to Week 12. Other outcomes included ACR50 response. The primary endpoint was met at Week 12. ACR50 response was met and favoured Cosentyx-treated patients against placebo at Week 12 (ACR50 responders 46% and 8% for Cosentyx and placebo, respectively; [odds ratio (95% CI): 10 (4, 24), p<0.0001, relative risk: 5]). The results were sustained at Week 52 (ACR50 responders 68% for Cosentyx and 72% for placebo-Cosentyx group, based on observed data with no statistical significance).[4,5]

[§]MEASURE 1 (N=361) was a randomised, double-blind, placebo-controlled, 2-year, Phase III study with a 3-year extension (N=274). Patients with AS were randomised to receive intravenous Cosentyx 10 mg/kg followed by subcutaneous Cosentyx 150 mg or 75 mg every 4 weeks, or matched placebo (N=122). Clinical efficacy assessments at Week 260 included ASAS criteria 20 and ASAS40 response; BASDAI50 response. The efficacy endpoints of the ASAS20 and ASAS40 responses were sustained through 5 years in patients who were originally randomised to Cosentyx 150 mg (data observed through 5 years in patients originally randomised to Cosentyx 150 mg without placebo switchers or patients whose dose was escalated). The BASDAI50 responses were improved in patients whose dose was escalated from Cosentyx 75 to 150 mg from 55.7% at Week 52 to 63.4 to Week 260. Percentages calculated from the proportion of patients.[6]

[¶]FUTURE 2 (N=397) was a randomised, double-blind, placebo-controlled, 52 weeks, Phase III trial in patients with active PsA, followed by a 5-year (end-of-study) analysis on efficacy and safety of Cosentyx across doses and dose escalation. Patients received Cosentyx 300 mg, 150 mg or 75 mg or placebo once a week from baseline and then every 4 weeks from Week 4. The primary endpoint was the proportion of patients achieving an ACR20 response at Week 24. Secondary endpoints included the resolution of dactylitis and enthesitis. The primary endpoint was met with all Cosentyx doses. Sustained improvements in the resolution of dactylitis (87.5%) and enthesitis (76.5%) were observed in the Cosentyx 300 mg arm (N=145) at Week 260. As observed analysis, no p-values reported. Percentages calculated from the proportion of patients.[7,13]

ACR, American College of Rheumatology; AS, ankylosing spondylitis; ASAS, Assessment of Spondyloarthritis International Society; axSpA, axial spondyloarthritis; BASDAI50, 50% improvement or more of the initial Bath ankylosing spondylitis disease activity index; CI, confidence interval; EULAR, European Alliance of Associations for Rheumatology; GLOESS, global EULAR and OMERACT synovitis score; IGA, investigator's global assessment; NAPSI, nail psoriasis severity index; OMERACT, outcome measures in rheumatology; PASI, psoriasis area severity index; PsA, psoriatic arthritis; PsO, moderate-to-severe plaque psoriasis; PSSI, psoriasis scalp severity index; SmPC, summary of product characteristics.

References: 1. Sigurgeirsson B, et al. *Dermatol Ther* 2022;35(3):e15285; **2.** Reich K, et al. *Br J Dermatol* 2019;181(5):954–966; **3.** Reich K, et al. *Br J Dermatol* 2021;184(3):425–436; **4.** D'Agostino MA, et al. *Rheumatology* (Oxford) 2022;61(5):1867–1876; **5.** Conaghan PG, et al. Poster 253. *Rheumatology* 2022:61(Suppl 1):1; **6.** Baraliakos X, et al. *RMD Open* 2019;5(2):e001005; **7.** McInnes IB, et al. *Lancet Rheumatol* 2020;2:e227–e235; **8.** Novartis Data on File. Secukinumab (Sec008) February 2023; **9.** Cosentyx® (secukinumab) Summary of Product Characteristics; **10.** Coates LC, et al. *Nat Rev Rheumatol* 2022;18(12):734; **11.** Braun J, et al. *Ther Adv Musculoskel Dis* 2021;13:1–18; **12.** Baeten D, et al. *N Engl J Med* 2015;373:2534–2548; **13.** McInnes IB, et al. *Lancet* 2015;386:1137–1146.