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

Cosentyx® secukinumab

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

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]

UK | December 2023 | 304685

NOVARTIS

How could Cosentyx benefit your eligible patients?

Symptom relief from all six key manifestations of PsA, all 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 GB 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.

Cosentyx® (secukinumab) Great Britain Prescribing Information.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Indications: Treatment of: moderate to severe plaque psoriasis in adults, children and adolescents 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 (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) 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. **Presentations:** Cosentyx 75 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled pen; Cosentyx 300 mg solution for injection in pre-filled pen. **Dosage & Administration:** Administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consider discontinuation if no response after 16 weeks of treatment. Each 75 mg dose is given as one injection of 75 mg. Each 150 mg dose is given as one injection of 150 mg. Each 300 mg dose is given as two injections of 150 mg or one injection of 300 mg. If possible avoid areas of the skin showing psoriasis. *Plaque Psoriasis:* Adult recommended dose is 300 mg. Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher. Adolescents and children from the age of 6 years: if weight ≥ 50 kg, recommended dose is 150 mg (may be increased to 300 mg as some patients may derive additional benefit from the higher dose). If weight < 50 kg, recommended dose is 75 mg. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNFα inadequate responders, the recommended dose is 300 mg, 150 mg in other patients. Can be increased to 300 mg based on clinical response. *Ankylosing Spondylitis:* Recommended dose 150 mg. Can be increased to 300 mg based on clinical response. *nr-axSpA:* Recommended dose 150 mg. *Enthesitis-related arthritis and juvenile psoriatic arthritis:* From the age of 6 years, if weight ≥ 50 kg, recommended dose is 150 mg. If weight < 50 kg, recommended dose is 75 mg. *Hidradenitis suppurativa:* Recommended dose is 300 mg monthly. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks. **Contraindications:** Hypersensitivity to the active substance or excipients. Clinically important, active infection. **Warnings & Precautions:** *Infections:* Potential to increase risk of infections; serious infections have been observed. Caution in patients with chronic infection or history of recurrent infection. Advise patients to seek medical advice if signs/symptoms of infection occur. Monitor patients with serious infection closely and do not administer Cosentyx until the infection resolves. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab in the psoriasis clinical studies. Should not be given to patients with active tuberculosis (TB). Consider anti-tuberculosis therapy before starting Cosentyx in patients with latent TB. *Inflammatory bowel disease (including Crohn's disease and ulcerative colitis):* New cases or exacerbations of inflammatory bowel disease have been reported with secukinumab. Secukinumab, is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, secukinumab should be discontinued and appropriate medical management should be initiated. *Hypersensitivity reactions:* Rare cases of anaphylactic reactions have been observed. If an anaphylactic or serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. *Vaccinations:* Do not give live vaccines concurrently with Cosentyx; inactivated or non-live vaccinations may be given. Paediatric patients should receive all age appropriate immunisations before treatment with Cosentyx. *Latex-Sensitive Individuals:* The removable needle cap of the 75mg and 150 mg pre-filled syringe and 150mg pre-filled pen contains a derivative of natural rubber latex. *Concomitant immunosuppressive therapy:* Combination with immunosuppressants, including biologics, or phototherapy has not been evaluated in psoriasis studies. Cosentyx was given concomitantly with methotrexate, sulfasalazine and/or corticosteroids in arthritis studies. Caution when considering concomitant use of other immunosuppressants. **Interactions:** Live vaccines should not be given concurrently with secukinumab. No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in adult psoriasis study. No interaction between Cosentyx and methotrexate and/or corticosteroids seen in arthritis studies. **Fertility, pregnancy and lactation:** *Women of childbearing potential:* Use an effective method of contraception during and for at least 20 weeks after treatment. *Pregnancy:* Preferably avoid use of Cosentyx in pregnancy. *Breast feeding:* It is not known if secukinumab is excreted in human breast milk. A clinical decision should be made on continuation of breast feeding during Cosentyx treatment (and up to 20 weeks after discontinuation) based on benefit of breast feeding to the child and benefit of Cosentyx therapy to the woman. *Fertility:* Effect on human fertility not evaluated. **Adverse Reactions**: *Very Common (≥1/10):* Upper respiratory tract infection. *Common (≥1/100 to <1/10):* Oral herpes, headache, rhinorrhoea, diarrhoea, nausea, fatigue. *Uncommon (≥1/1,000 to <1/100):* Oral candidiasis, lower respiratory tract infections, neutropenia, inflammatory bowel disease. *Rare (≥1/10,000 to <1/1,000):* anaphylactic reactions, exfoliative dermatitis (psoriasis patients), hypersensitivity vasculitis. *Not known:* Mucosal and cutaneous candidiasis (including oesophageal candidiasis). *Infections:* Most infections were non-serious and mild to moderate upper respiratory tract infections, e.g. nasopharyngitis, and did not necessitate treatment discontinuation. There was an increase in mucosal and cutaneous (including oesophageal) candidiasis, but cases were mild or moderate in severity, non-serious, responsive to standard treatment and did not necessitate treatment discontinuation. Serious infections occurred in a small proportion of patients (0.015 serious infections reported per patient year of follow up). *Neutropenia:* Neutropenia was more frequent with secukinumab than placebo, but most cases were mild, transient and reversible. Rare cases of neutropenia CTCAE Grade 4 were reported. *Hypersensitivity reactions:* Urticaria and rare cases of anaphylactic reactions were seen. *Immunogenicity:* Less than 1% of patients treated with Cosentyx developed antibodies to secukinumab up to 52 weeks of treatment. *Other Adverse Effects:* The list of adverse events is not exhaustive, please consult the SmPC for a detailed listing of all adverse events before prescribing. **Legal Category:** POM. **MA Number & List Price:** PLGB 00101/1205 – 75 mg pre-filled syringe x 1 - £304.70; PLGB 00101/1029 - 150 mg pre-filled pen x2 £1,218.78; PLGB 00101/1030 - 150 mg pre-filled syringe x2 £1,218.78; PLGB 00101/1198 – 300 mg pre-filled pen x 1 £1218.78. **PI Last Revised:** June 2023. Full prescribing information, (SmPC) is available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

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Adverse Event Reporting:

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 via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report.

If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com