

Your guide to flexible dosing with Cosentyx® (secukinumab)

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 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.¹

Please refer to the Cosentyx Summary of Product Characteristics (SmPC) for further information about the clinical indications.¹



Convenience of a monthly injection with Cosentyx after initial loading doses

Recommended dosage per indication after initial dosing at Weeks 0, 1, 2, 3 and 4:1

Psoriatic arthritis (PsA) alone or in combination with MTX

Indication	150 mg monthly	300 mg monthly	300 mg Q2W
PsA biologic naïve (First-line biologic)	√ Up-tit	tration	
PsA switch (inadequate response to anti-TNF α)		✓	
PSA with concomitant moderate to severe PsO		√ - Up-titra	> ≥90 kg*

Axial spondyloarthritis (AxSpA)

Indication	150 mg monthly	300 mg monthly	
Ankylosing spondylitis (AS)	√ Up-tit	ration	
Non-radiographic-AxSpA	✓		

Juvenile idiopathic arthritis (JIA) alone or in combination with MTX

Indication	75 mg monthly	150 mg monthly
Enthesitis-related arthritis (ERA)	<50 kg*	≥50 kg*
Juvenile psoriatic arthritis (JPsA)	<50 kg*	≥50 kg*

Moderate to severe plaque psoriasis (PsO)

Indication	75 mg monthly	150 mg monthly	300 mg monthly	300 mg Q2W
Ps0			√ Up-	titration ≥90 kg*
Paediatric Ps0 (≥6 years)	<50 kg*	≥50 kg* Up-tif	ration ≥50 kg*	

Depending on a patient's clinical response, up-titration may be prescribed at any point during the treatment journey with Cosentyx¹

AS, ankylosing spondylitis; AxSpA, axial spondyloarthritis; ERA, enthesitis-related arthritis; JIA, juvenile idiopathic arthritis; JPsA, juvenile psoriatic arthritis; MTX, methotrexate; nr-axSpA, non-radiographic axial spondyloarthritis; PsA, psoriatic arthritis; PsO, plaque psoriasis; Q2W, every 2 weeks.

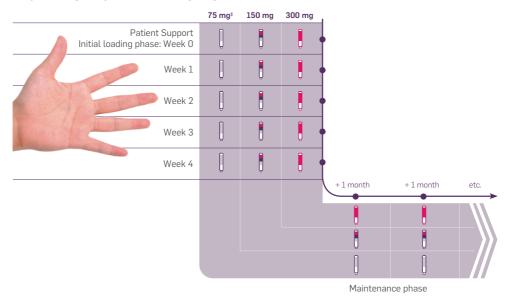
^{*}Body weight at time of dosing.1

A flexible dosing schedule with Cosentyx

The 'hand rule' of Cosentyx dosing

Cosentyx is administered by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing.^{†1}

Depending on patient dosing regimen:





Individual patient dosing may vary - please consult the Summary of Product Characteristics for full details.1

Patients may self-inject Cosentyx or be injected by a caregiver. After proper training in subcutaneous injection technique, patients may self-inject Cosentyx or be injected by a caregiver if a physician determines that this is appropriate. The physician should ensure appropriate follow-up of patients. Patients or caregivers should be instructed to inject the full amount of Cosentyx according to the instructions provided in the package leaflet. Comprehensive instructions for administration are given in the package leaflet. ¹

[‡]Pre-filled syringe for paediatric patients.

Reference

Cosentyx GB Summary of Product Characteristics.

Cosentyx® (secukinumab) Great Britain Prescribing Information. Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Indications: Treatment of: moderate to severe plague 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. *Plague 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 plague psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNFa 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 preexisting 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 ($\geq 1/10,000$ 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.

UK | 290802 | June 2023

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