

Cosentyx® (secukinumab) Prescribing Information.

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

Indications: Treatment of: moderate to severe plaque psoriasis in adults 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.

Presentations: Cosentyx 150 mg solution for injection in pre-filled syringe; Cosentyx 150 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 300 mg dose is given as two injections of 150 mg. **Plaque Psoriasis:** Recommended dose 300 mg – if possible avoid areas of the skin showing psoriasis. **Psoriatic Arthritis:** Recommended doses are 300 mg in patients with concomitant moderate to severe plaque psoriasis or who are anti-TNF α inadequate responders, 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.

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 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. **Latex-Sensitive Individuals:** The removable needle cap of the pre-filled syringe and 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: No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in a 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** ($\geq 1/10$): Upper respiratory tract infection. **Common** ($\geq 1/100$ to $< 1/10$): Oral herpes, Tinea pedis, rhinorrhoea, diarrhoea. **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). **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:** Please consult the SmPC for a detailed listing of all adverse events before prescribing.

Legal Category: POM.

MA Number & List Price: EU/1/14/980/005 - 150 mg pre-filled pen x2 £1,218.78; EU/1/14/980/003 - 150 mg pre-filled syringe x2 £1,218.78.

PI Last Revised: July 2020. COS20-C071. 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.

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 Patient Safety Information (PSI) tool at <https://psi.novartis.com>.

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