Cosentyx▼ (secukinumab) Prescribing Information
Please refer to the Summary of Product Characteristics before prescribing.

Indication: Cosentyx is indicated for: the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy; the treatment of active psoriatic arthritis in adult patients, alone or in combination with methotrexate (MTX), when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate

Presentations: Cosentyx 150 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled pen.

Dosage & Method of Administration: *Psoriasis:* The recommended dose is 300 mg via subcutaneous injection. Dosing is given at weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. Each 300 mg dose is given as two subcutaneous injections of 150 mg. If possible, areas of the skin that show psoriasis should be avoided as injection sites. *Psoriatic Arthritis:* For patients with concomitant moderate to severe plaque psoriasis or who are anti-TNFα inadequate responders (IR), the recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. Each 300 mg dose is given as two subcutaneous injections of 150 mg. For other patients, the recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing starting at Week 4. Consideration should be given to discontinuing treatment in patients who have shown no response up to 16 weeks of treatment. Some patients with an initial partial response may subsequently improve with continued treatment beyond 16 weeks. Safety and efficacy in patients below the age of 18 years have not been established.

Contraindications: Severe hypersensitivity reactions to the active substance or to any of the excipients. Clinically important, active infection.

Warnings & Precautions: *Infections:* Cosentyx has the potential to increase the risk of infections. In clinical studies, most of these were mild or moderate upper respiratory tract infections such as nasopharyngitis and did not require treatment discontinuation. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab than placebo in the psoriasis clinical studies. Caution in patients with a chronic infection or a history of recurrent infection. Advise patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops a serious infection, the patient should be closely monitored and Cosentyx should not be administered until the infection resolves. Cosentyx should not be given to patients with active tuberculosis. Anti-tuberculosis therapy should be considered prior to initiation of Cosentyx in patients with latent tuberculosis. *Crohn's disease:* Caution in patients with Crohn's disease - exacerbations of Crohn's disease, in some cases serious, were observed in clinical studies. Patients who are treated with Cosentyx and have Crohn's disease should be followed closely. *Hypersensitivity reactions:* Rare cases of anaphylactic reactions have been observed. If anaphylactic or other serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. *Vaccinations:* Live vaccines should not be given concurrently with Cosentyx. Patients receiving Cosentyx may receive concurrent inactivated or non-live vaccinations. *Latex-Sensitive Individuals:* The removable needle cap of the Cosentyx pre-filled syringe and the pre-filled pen contains a derivative of natural rubber latex. *Concomitant immunosuppressive therapy:* Combination with immunosuppressants, including biologics, or phototherapy - have not been evaluated.

Interactions: Live vaccines should not be given concomitantly with Cosentyx. No interaction studies have been performed in humans. The formation of some CYP450 enzymes are suppressed by increased levels of cytokines during chronic inflammation. Thus normalisation of CYP450 levels may be anticipated during secukinumab treatment, with accompanying lower exposure of CYP450 metabolised co-medications. Therefore, a clinically relevant effect on CYP450 substrates with a narrow therapeutic index, where the dose is individually adjusted (e.g. warfarin) cannot be excluded. On initiation of secukinumab therapy in patients being treated with these types of medicinal products, therapeutic monitoring should be considered. No interaction was seen when Cosentyx was administered concomitantly with methotrexate and/or corticosteroids in arthritis studies.

Fertility, pregnancy and lactation: *Women of childbearing potential:* Women of childbearing potential should use an effective method of contraception during treatment and for at least 20 weeks after treatment. *Pregnancy:* It is preferable to avoid the use of Cosentyx in pregnancy, due to lack of adequate data. *Breast feeding:* Clinical decision on continuation of breast feeding during secukinumab treatment (and up to 20 weeks after discontinuation) in nursing mothers must be made, taking into account the benefit of breast feeding to the child and the benefit of Cosentyx therapy to the woman. It is not known if secukinumab is excreted in human breast milk. *Fertility:* The effect of secukinumab on human fertility has not been evaluated.

Adverse Events: *Very Common* (≥1/10)*:* Upper respiratory tract infection. *Common* (≥1/100 to <1/10)*:* Oral herpes, rhinorrhoea, diarrhoea. *Rare (≥1/10,000 to <1/1,000)*: anaphylactic reactions. *Infections:* In the placebo controlled period of clinical studies in plaque psoriasis, infections were reported. The majority of infections consisted of non-serious and mild to moderate upper respiratory tract infections, such as nasopharyngitis, which did not necessitate treatment discontinuation. There was an increase in mucosal or cutaneous candidiasis, but the 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 in both the Cosentyx and placebo groups. Over the entire treatment period (up to 52 weeks), infections were reported in 47.5% of patients treated with Cosentyx (0.9 per patient year of follow up). Serious infections were reported in 1.2% of patients treated with Cosentyx (0.015 per patient years of follow up). Infection rates observed in psoriatic arthritis clinical studies were similar to those observed in the psoriasis studies *Neutropenia:* Neutropenia was more frequently observed with secukinumab than with placebo, but most cases were mild, transient and reversible. The frequency of neutropenia in psoriatic arthritis is similar to psoriasis. Rare cases of neutropenia CTCAE Grade 4 were reported. *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 Summary of Product Characteristics 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: December 2015 [COS15-C128]

Full prescribing information, including a SmPC is available from: Novartis Pharmaceuticals UK Limited, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR. Telephone: (01276) 692255 Fax: (01276) 692508**.**

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 Pharmaceuticals UK Ltd on 01276 69 8370 or via medinfo.uk@novartis.com.