

University of Dundee

## Artificial intelligence-ready skin cancer alchemy

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**BT02 Artificial intelligence-ready skin cancer alchemy: transforming routine teledermatology data into metadata-embedded DICOM files**

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Most skin artificial intelligence (AI) classifiers are trained only on images with diagnostic labels. However, the addition of clinical information can improve predictive accuracy. Recent interest has been stimulated in incorporating clinical data into image files, using the well-established international Digital Imaging and Communication in Medicine (DICOM) standards (Caffery L, Weber J, Kurtansky N *et al.* DICOM in dermoscopic research: experience report and a way forward. *J Digit Imaging* 2021; **34**: 967–73). We have developed an automated process of creating metadata-embedded DICOM files, directly from a live teledermatology system, described below. Through our Community and Locality Imaging Centre (CLIC) model, patients referred from primary care are triaged to CLIC for high-quality image capture. There, trained health professionals use a mobile application to capture standardized DICOM information for each lesion. Each lesion dataset contains images (macroscopic,

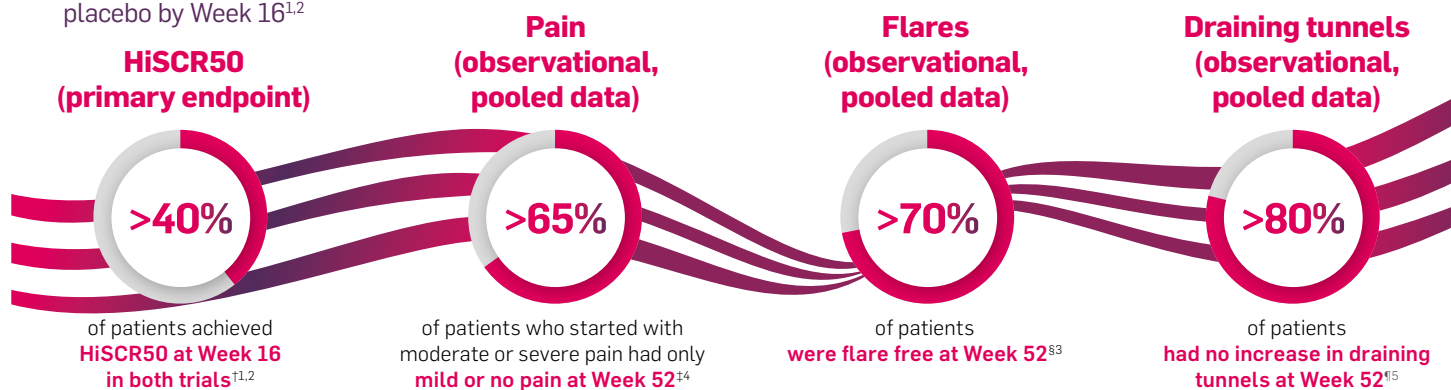
dermoscopic) and clinical metadata (patient and lesion information). Datasets are transferred to an image management system, for teledermatology and verification of ground-truth diagnoses by a consultant dermatologist. On completion of diagnoses, datasets are flagged for conversion into DICOM format, where metadata are embedded in the image files. Flagged datasets are cleaned and clinical metadata are mapped to DICOM attributes. Datasets are converted into metadata-embedded DICOM files, and reviewed for conformance to the DICOM standard using the open-source fo-dicom library (v5). These files are further tested for conformance to DICOM standard using the dciodvfy validator tool. Compliant DICOM files are then transferred to a trusted research environment for research. To test whether these DICOM files are usable for AI research, they are examined using the DICOM viewing software 3D Slicer (<https://www.slicer.org/>), ensuring images are usable and metadata are correctly translated. Image pixel data and clinical metadata are extracted using pydicom, into a format suitable for AI algorithm development. In our pilot work, 658 lesion datasets have been converted into metadata-embedded DICOM files. Conversion on existing hardware [virtual Intel central processing units with 2.60 GHz (two processors) and 8 GB of memory] took < 1 s per image. Metadata-embedded DICOM files were approximately 0.2 kB bigger than the original JPEG files. For 3-MB images, this represented a negligible 0.003% increase in storage requirement. Testing has shown that these files can be successfully handled by algorithms within an AI research environment. In summary, we have demonstrated the feasibility of automating the conversion of routine teledermatology data into AI-ready image files encoded with clinical metadata. Future work is planned to evaluate the utility of this output on the performance of AI classifiers.

# Cosentyx<sup>®</sup> (secukinumab) is available for eligible patients with moderate to severe hidradenitis suppurativa (HS)<sup>\*1,2</sup>

Cosentyx can help to provide **fast relief and lasting control** for your eligible patients with HS<sup>3</sup>

**FAST:** Improved outcomes in HiSCR50 vs placebo by Week 16<sup>1,2</sup>

**LASTING:** Improved outcomes lasted through Week 52 (observed data with no statistical testing)<sup>3-5</sup>



The primary endpoint was met for Cosentyx 300 mg Q2W in both SUNRISE and SUNSHINE ( $p=0.015$  and  $p=0.007$ , respectively) and was met for Cosentyx 300 mg Q4W in SUNRISE ( $p=0.002$ ), but not in SUNSHINE.<sup>4</sup>

The most frequently reported adverse reactions are upper respiratory tract infections (17.1%) (most frequently nasopharyngitis, rhinitis).<sup>1,2</sup>

### No new safety signals observed in HS trials<sup>3</sup>

The most frequently reported adverse events in SUNSHINE and SUNRISE were headache, nasopharyngitis and worsening of hidradenitis up to Week 16.<sup>3</sup>

Please consult the SmPC before prescribing.

**Cosentyx is recommended by NICE** as an option for the treatment of moderate to severe HS in adults who have not responded to conventional systemic treatment (subject to eligibility criteria)<sup>6</sup>



**Cosentyx is approved for use in eligible patients with HS<sup>1,2</sup>**

Click here to find out more

**Cosentyx licensed indications in dermatology:** Cosentyx is indicated for the 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 moderate to severe **HS** (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. For full indications, please see the SmPC.<sup>1,2</sup>

**SUNSHINE AND SUNRISE:** Two randomised, double-blind, multicentre, Phase III trials: SUNSHINE and SUNRISE (Cosentyx 300 mg Q4W,  $n=360$  or Cosentyx 300 mg Q2W,  $n=361$ ). The primary endpoint for both SUNSHINE and SUNRISE studies in adult patients with moderate to severe HS was the clinical response (as measured by HiSCR), defined as a decrease in abscess and inflammatory nodule count by 50% or more with no increase in the number of abscesses or draining fistulae compared with baseline, of Cosentyx versus placebo at Week 16, assessed in the overall population. Clinical response was sustained to Week 52 in both trials.<sup>4</sup>

\*Cosentyx is indicated in adult patients with moderate to severe HS (acne inversa) with an inadequate response to conventional HS therapy.<sup>1,2</sup> Please see above for the licensed dermatology indications.

<sup>1</sup>HiSCR50:  $\geq 50\%$  decrease in abscesses and inflammatory nodules count with no increase in the number of abscesses and/or in the number of draining fistulae relative to baseline at Week 16. In HS study 1 HiSCR50 was 41.8% and 45.0% in the Q4W arm ( $n=180$ ) and Q2W arm ( $n=181$ ), respectively. In HS study 2 HiSCR50 was 46.1% and 42.3% in the Q4W arm ( $n=180$ ) and Q2W arm ( $n=180$ ), respectively.<sup>1,2</sup>

<sup>4</sup>The percentage of patients who started with moderate or severe pain and had mild or no pain was 65.3% in the Cosentyx group and 80.9% in the placebo group for the Q2W dosing regimen. The percentage of patients who started with moderate or severe pain and had mild or no pain at Week 52 was 70.1% in the Cosentyx group and 64.8% in the placebo group for the Q4W dosing regimen.<sup>3</sup>

<sup>8</sup>Flare, a prespecified exploratory endpoint, is defined as at least a 25% increase in AN count with a minimum increase of 2 in absolute AN count relative to baseline. In the Q4W arm, 360 patients were evaluable at Week 16 and 278 patients were evaluable at Week 52, 27.3% of patients experienced flares at Week 52. In the Q2W arm, 361 and 289 were evaluable at Week 16 and Week 52, respectively with 20.4% of patients experiencing flares at Week 52.<sup>4</sup>

<sup>15</sup>Observed data from full analysis set. Number of patients with no increase from baseline from Week 16 to Week 52 in patients with at least one draining fistulae at baseline. 82.6% in Q4W arm ( $n=218$ ), 80.7% in Q2W arm ( $n=239$ ).<sup>5</sup>

**Abbreviations:** AN, abscess and inflammatory nodule; HiSCR, hidradenitis suppurativa clinical response; HS, hidradenitis suppurativa; Q2W, every 2 weeks; Q4W, every 4 weeks; SmPC, summary of product characteristics.

**References:** **1.** Cosentyx<sup>®</sup> (secukinumab) GB Summary of Product Characteristics; **2.** Cosentyx<sup>®</sup> (secukinumab) NI Summary of Product Characteristics; **3.** Kimball AB, et al. *Lancet* 2023;401(10378):747-761 and supplementary appendix; **4.** Novartis Data on File. SUNNY clinical programme post-hoc analysis of skin pain severity. March 2023; **5.** Novartis Data on File. Draining fistulas; **6.** National Institute for Health and Care Excellence. Secukinumab for treating moderate to severe hidradenitis suppurativa. Available at: <https://www.nice.org.uk/guidance/ta935> [Accessed April 2024].

Prescribing information and adverse event reporting can be found on the next page.

## Cosentyx® (secukinumab) Northern Ireland 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 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 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 monthly. 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  $\geq$  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. However, 150mg solution for injection in pre-filled pen is not indicated for administration of this dose and no suitable alternative formulation is available. **Psoriatic Arthritis:** For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNF $\alpha$  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  $\geq$  50 kg, recommended dose is 150 mg. If weight

## 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  $\geq$  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-TNF $\alpha$  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  $\geq$  50 kg, recommended dose is 150 mg. If weight

$<$  50 kg, recommended dose is 75 mg. However, 150mg solution for injection in pre-filled pen is not indicated for administration of this dose and no suitable alternative formulation is available. **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 than placebo 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 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

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

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, headache, rhinorrhoea, diarrhoea, nausea, fatigue. *Uncommon* ( $\geq$ 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:** EU/1/14/980/005 - 150 mg pre-filled pen x2 £1,218.78; EU/1/14/980/010 - 300 mg pre-filled pen x1 £1218.78. **PI Last Revised:** May 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 I 284832 | May 2023

### Adverse Event Reporting:

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Novartis via [uk.patientsafety@novartis.com](mailto:uk.patientsafety@novartis.com) or online through the pharmacovigilance intake (PVI) tool at [www.novartis.com/report](http://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](mailto:medinfo.uk@novartis.com)

human fertility not evaluated. **Adverse Reactions:** *Very Common* ( $\geq$ 1/10): Upper respiratory tract infection. *Common* ( $\geq$ 1/100 to  $<$ 1/10): Oral herpes, headache, rhinorrhoea, diarrhoea, nausea, fatigue. *Uncommon* ( $\geq$ 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 x1 - £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 x1 £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 I 290802 | June 2023

### Adverse Event Reporting:

Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to Novartis via [uk.patientsafety@novartis.com](mailto:uk.patientsafety@novartis.com) or online through the pharmacovigilance intake (PVI) tool at [www.novartis.com/report](http://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](mailto:medinfo.uk@novartis.com)