Br J Dermatol 2024; **00**:1–2
https://doi.org/10.1093/bjd/ljae190
Advance access publication date: 13 May 2024

BJD
British Journal of Dermatology
Research Letter

‘Feeling like a second-class citizen’: exploring the impact, self-management and existing support for adults living with acne and/or post-inflammatory hyperpigmentation and scarring

Dear Editor, Acne vulgaris, a common inflammatory skin condition, affects at least 10% of people worldwide.[1] Many develop post-inflammatory hyperpigmentation and scarring (PIH&S) that persists long after acne symptoms have cleared. The physical, psychological and social burden of acne is well recognized,[2] but research on the life impact of acne PIH&S is scarce.[3]

People with skin conditions often struggle to manage the psychological aspects of their condition[2] and often use health-threatening behaviours to cope.[4] However, psychological support, including behavioural change, for patients is lacking. Acne Action Canada is currently the only organization dedicated to supporting people with acne and PIH&S.

We are developing a complex digital behaviour change intervention (DBCI) for adults living with skin conditions and conducted qualitative research involving adults with acne and PIH&S to guide the intervention and ensure its relevance for this population.

We conducted individual semi-structured interviews with eight adults (seven females) with acne and/or PIH&S [mean age 34.5 years (SD 11.07); mean duration of condition 21.3 years (SD 11.29)]. Participants were recruited via social media using convenience and voluntary sampling with support from five patient organizations. Data collection and analysis were theoretically informed by the Common-Sense Model of Self-Regulation (CSM).[5] The interview topic guide addressed the impact, self-management of, and existing support available for, acne and PIH&S. Data were analysed using framework analysis.[6]

Four superordinate themes and two subthemes were derived from the data (Table 1):

1 Acne blame
  1a Social consequences
  1b Psychological consequences
2 Control at any cost
3 The business of skinfluencers
4 ‘It’s your hormones’

Public stigma around acne and PIH&S, particularly misconceptions around causes and triggers (e.g. poor personal hygiene, poor diet or picking skin) exacerbated psychological distress, self-stigma and influenced coping through social withdrawal. Participants described the development of scarring as ‘*traumatic*’ (female, 29 years, Wales). Some shared concerns about PIH&S symptoms persisting following successful treatment, and others felt disheartened over the permanency of scarring following acne clearance.

Visible symptoms of PIH&S were difficult to cover or conceal. Inadequate medical support led to an urgency to control symptoms with some participants using harmful behaviours, including overuse of prescribed antibiotics and use of needles to pick acne, in an attempt to clear their skin. Many participants searched for self-management guidance online but questioned the quality of information available. They also relied on social media accounts for advice but explained how critical comments directed at ‘skinfluencers’ negatively affected their personal wellbeing. Some participants appreciated the value of self-acceptance and the normalization of skin conditions on social media.

Female participants reported the impact of acne and PIH&S was exacerbated by unpredictability of symptoms during the menstrual cycle, pregnancy, menopause and use of hormonal contraception. One participant also expressed frustration at the lack of understanding among health professionals over the relationship between acne and polycystic-ovary syndrome.

Not only does this study highlight the life impact of acne and PIH&S, it also emphasizes that people can experience persistent psychological scarring.

Participants wanted support with self-management, but professional support was lacking. Evidence-based guidance for self-management from trustworthy sources is needed, as is funding to establish new patient organizations representing people living with acne and PIH&S. In addition, tailored guidance and interventions are required to address the additional impacts that women experience.

Our results demonstrate the impact of public stigma and misconceptions regarding acne and PIH&S on self-stigma, self-acceptance and other psychological outcomes. We call for public health campaigns aiming to raise awareness and understanding of these conditions to help reduce public and self-stigma in those who live with them.[7]

The findings highlight the potential dangers of relying on the internet and social media for self-management support. Strategies are needed to moderate and improve the quality of information being circulated through online ‘skincare’ accounts and websites. Clinicians should direct patients to seek guidance from established, credible sources.

Despite their strong theoretical grounding, these results should be interpreted with caution due to the small, gender-biased sample.[8] However, theme coverage was achieved in this sample with several, if not all, participants contributing to each theme. This study highlights a wider issue in recruitment of people with acne and PIH&S in dermatology research and new approaches are needed to engage this population.

Accepted: 4 May 2024

Table 1 Themes, subthemes and illustrative extracts, informed by the Common-Sense Model of Self-Regulation (CSM)

Theme/subthemes	CSM concept	Extract
1. Acne blame		
1a. Social consequences	Social consequences	*'I'm just not going to do it [approach other women socially]. Because I … I'll just … I won't talk to anyone, I'll be [in] a bad mood, um, I won't feel confident to … to speak to people. Um, I … in my teen years, because um, because I wasn't um, classed as pretty or attractive to the other girls, um, I wasn't friends with any girls in high school'* (Female, 41 years, Wales)
1b. Psychological consequences	Psychological consequences	*'The mental health aspect of it has been … it's been pretty brutal, you kind of feel like, almost like you're a second-class citizen, and you aren't good enough. I've had um, episodes where I've just been crying for days and days, you know, why is this happening to me, why can't I just …, just … just no more acne, that's … that's all I want…'* (Female, 44 years, Wales)
2. Control at any cost	Control and curability	*'I used to overdose on my antibiotics […] I'd just hit this point of crisis and just take loads … I was a naïve teenager and I mean I wouldn't do that now, but I just wanted rid of the spots 'cause I was being so horrendously bullied about them'* (Female, 29 years, Wales)
3. The business of skinfluencers	Personal control, seeking information for self-management	*'I think social media is a difficult thing to be because you're, you're not just having the people in your life making those comments, it's like the whole world could make comments like that [laughs] and whilst they might not be making them to me, they're making them to another acne sufferer, erm, then it's like it's just as bad 'cause you think, oh they maybe think that about my skin too …'* (Female, 29 years, Wales)
4. 'It's your hormones'	Control and curability, treatment consequences	*'It would just send me into this spiral of despair about my skin and all this whilst you're trying for a baby as well, so [laughs] you're, you're in this dilemma, I really want to try for a baby, erm, I know this is, erm, important for our life and our future, but, er, I just want to go back on my medication 'cause I know that helps my skin and I'll be back to my normal self.'* (Female, 29 years, Wales)

In conclusion, living with acne has a significant impact, and the presence of PIH&S creates additional burden. Those living with acne and PIH&S should be supported to seek evidence-based guidance on helpful and safe methods of self-management. These results will inform the development of a new DBCI for adults with skin conditions.

Carys Dale[1], **Rachael M. Hewitt**[1], **Catherine Purcell**[1], **Neesha Pandya**[2] **and Chris Bundy**[1]

[1]School of Healthcare Sciences, Cardiff University, Cardiff, Wales, UK and [2]Patient and Public Involvement Contributor

Correspondence: Carys Dale. Email: dalec3@cardiff.ac.uk

Acknowledgements: We are grateful to the following patient organizations that supported participant recruitment: The International Alliance of Dermatological Patient Organizations; Skin Care Cymru; and The British Skin Foundation. Thank you to our Patient and Public Involvement contributors for their input in the design, promotion and write-up of this study. Finally, thank you to the people who took part in this study and shared their experiences.

Funding sources: This study is funded by Beiersdorf.

Conflicts of interest: RMH has received financial support for research from Beiersdorf AG. Over the last 3 years CB has received funds for research, honoraria or consultancy from the following pharmaceutical companies: Abbvie, Almirall, Amgen (was Celgene), Beiersdorf AG, Janssen, Novartis, Pfizer and UCB.

Data availability: The data underlying this article will be shared on reasonable request to the corresponding author.

Ethics statement: Not applicable.

References

1 Layton AM, Thiboutot D, Tan J. Reviewing the global burden of acne: how could we improve care to reduce the burden? *Br J Dermatol* 2021; **184**:219–25.
2 Pattinson R, Hewitt RM, Trialonis-Suthakharan N *et al.* Development of a conceptual framework for a Patient-Reported Impact of Dermatological Diseases (PRIDD) measure: a qualitative concept elicitation study. *Acta Derm Venereol* 2022; **102**:adv00823. https://doi.org/10.2340/actadv.v102.2401.
3 Tan J, Beissert S, Cook-Bolden F *et al.* Evaluation of psychological well-being and social impact of atrophic acne scarring: a multinational, mixed-methods study. *JAAD Int* 2022; **6**:43–50.
4 Gerdes S, Zahl VA, Weichenthal M *et al.* Smoking and alcohol intake in severely affected patients with psoriasis in Germany. *Dermatology* 2009; **220**:38–43.
5 Leventhal H, Benyamini Y, Brownlee S *et al.* Illness representations: theoretical foundations. In: *Perceptions of Health and Illness: Current research and applications*. Amsterdam, the Netherlands: Harwood Academic Publishers, 1997; 19–45.
6 Kiernan MD, Hill M. Framework analysis: a whole paradigm approach. *Qual Res J* 2018; **18**:248–61.
7 University of Manchester. Manchester Psoriasis Shout Out raising awareness of the skin condition psoriasis. 23 April 2014. Available from: https://www.manchester.ac.uk/discover/news/manchester-psoriasis-shout-out-raising-awareness-of-the-skin-condition-psoriasis/ (accessed 15 November 2023).
8 Coulson N. *Online Research Methods for Psychologists*. London: Palgrave, 2015.

Cosentyx® secukinumab

Cosentyx® (secukinumab) is available for eligible patients with moderate to severe hidradenitis suppurativa (HS)*[1,2]

Cosentyx can help to provide **fast relief and lasting control** for your eligible patients with HS[3]

FAST: Improved outcomes in HiSCR50 vs placebo by Week 16[1,2]

LASTING: Improved outcomes lasted through Week 52 (observed data with no statistical testing)[3–5]

HiSCR50 (primary endpoint)

>40%

of patients achieved **HiSCR50 at Week 16 in both trials**†[1,2]

Pain (observational, pooled data)

>65%

of patients who started with moderate or severe pain had only **mild or no pain at Week 52**‡[4]

Flares (observational, pooled data)

>70%

of patients **were flare free at Week 52**§[3]

Draining tunnels (observational, pooled data)

>80%

of patients **had no increase in draining tunnels at Week 52**¶[5]

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.[4]

The most frequently reported adverse reactions are upper respiratory tract infections (17.1%) (most frequently nasopharyngitis, rhinitis).[1,2]

No new safety signals observed in HS trials[3]

The most frequently reported adverse events in SUNSHINE and SUNRISE were headache, nasopharyngitis and worsening of hidradenitis up to Week 16.[3]

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)[6]

Cosentyx is approved for use in eligible patients with HS[1,2]

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.[1,2]

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.[4]

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

†HiSCR50: ≥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.[1,2]

‡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.[3]

§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.[4]

¶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).[5]

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® (secukinumab) GB Summary of Product Characteristics; **2.** Cosentyx® (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.

UK | April 2024 | 421564

NOVARTIS

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 ≥ 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-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. 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 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:** EU/1/14/980/005 - 150 mg pre-filled pen x2 £1,218.78; EU/1/14/980/010 – 300 mg pre-filled pen x 1 £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 | 284832 | May 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

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.

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