Measurement properties and interpretability of the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure

Running head: Measurement properties and interpretability of PRIDD

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

Ethics statement: Ethical approval was obtained from Cardiff University School of Healthcare Sciences Ethics Committee (SREC:826).

Patient consent: Informed consent was obtained from all participants.

What is already known about this topic?

Quantifying dermatological disease impact is fundamental to high quality research and clinical practice.

Existing dermatology-specific patient-reported outcome measures (PROMs) of impact cannot be recommended per the Consensus-Based Standards for the Selection of Health Measurement Instruments (COSMIN).

Developed in partnership with patients, the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure, for use with adults in research and clinical practice, has strong evidence of content validity, structural validity, internal consistency, acceptability, and feasibility.

What does this study add?

This study concluded the development and validation of the 16-item PRIDD. It established evidence of PRIDD's criterion validity, construct validity, test-retest reliability, measurement error and lack of floor and ceiling effects.

The results indicate that PRIDD is the only dermatology-specific PROM to meet the COSMIN criteria to be recommended for use.

We provide evidence-based score bandings for PRIDD total and subscale scores to aid interpretation in research and clinical practice.

What are the clinical implications of this work?

PRIDD is a valid, reliable, acceptable, and feasible tool to help clinicians to evaluate the impact of dermatological disease on patients' lives. It is suitable for use in both research and clinical practice.

PRIDD subscales can be combined or used individually to distinguish among domains of impact, making it a powerful and versatile tool for clinicians; supporting person-centred care and allowing for rapid referral to appropriate specialist care.

Abstract

Background: Patient-reported outcome measures (PROMs) are crucial for assessing the impact of dermatological conditions on patients' lives, but the existing dermatology-specific PROMs are not recommended for use according to the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN). We developed the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure in partnership with patients. It has strong evidence of content validity, structural validity, internal consistency, acceptability, and feasibility.

Objectives: To test PRIDD's remaining measurement properties and establish the interpretability of scores against the COSMIN criteria using classic and modern psychometric methods.

Methods: A global longitudinal study consisting of two online surveys administered two to four weeks apart. Adults (≥ 18 years) living with a dermatological condition were recruited through the International Alliance of Dermatology Patient Organizations' (GlobalSkin) membership network. Participants completed PRIDD, a demographics questionnaire, and other related measures including the Dermatology Life Quality Index (DLQI). We tested PRIDD's criterion validity, construct validity and responsiveness (Spearman's ρ, independent-samples t-tests and ANOVA), test-retest reliability (interclass correlation coefficient [ICC]), measurement error (Smallest Detectable Change or Limits of Agreement [LoA], distribution-based Minimally Important Change [MIC]), floor and ceiling effects (number of minimum and maximum scores and Person-Item Location Distribution Maps), score bandings (κ coefficient of agreement) and anchor-based MIC.

Results: 504 patients with 35 dermatological conditions from 38 countries participated. Criterion validity (ρ = 0.79), construct validity (76% hypotheses met), test-retest validity

(ICC = 0.93), and measurement error (LoA = 1.3 < MIC = 4.14) were sufficient. Floor and ceiling effects were in the acceptable range (< 15%). Score bandings were determined (κ = 0.47), however, the anchor-based MIC could not be calculated due to an insufficient anchor.

Conclusions: PRIDD is a valid and reliable tool to evaluate the impact of dermatological disease on patients' lives in research and clinical practice. It is the first dermatology-specific PROM to meet the COSMIN criteria. These results support the value of developing and validating PROMs with a patient-centred approach and using classic and modern psychometric methods. Further testing of responsiveness and MIC, cross-cultural translation, linguistic validation, and global data collection are planned.

Introduction

Dermatological diseases are highly prevalent and encompass a wide range of conditions that significantly impact patients' physical, psychological, and social well-being.1-6 Their symptoms are often distressing and uncomfortable, ranging from pain, itch, redness, scaling, and lesions to death and disfigurement. The detrimental effects extend beyond the often-visible symptoms and can substantially reduce overall wellbeing. Patients may experience psychological distress,7-12 stigmatisation,13-15 financial costs,16-19 impairments to daily functioning and activities,20 treatment-related problems,21 cumulative life course impairment,22-25 and comorbidities.3,4,26-29 Psychological distress may persist even after symptoms have cleared.3,30-33 The disease burden extends beyond the individual patient: families report emotional distress and caregiver burden,34,35 healthcare systems see high utilisation and costs, and society faces healthcare expenditure, productivity losses, and diminished overall societal wellbeing. 36-41 Understanding the multifaceted impact of dermatological diseases is crucial for developing comprehensive strategies that address the needs of patients, their families, healthcare systems, and society as a whole.

Since the 1990s, patient-reported outcome measures (PROMs), most notably the Dermatology Life Quality Index (DQLI),21 have transformed our understanding and management of dermatological conditions, paving the way for patient-centred care and improved treatment outcomes. Systematic reviews have found that no dermatology-specific (can be used across conditions) PROM of life impact meets the Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) to be recommended for use.42-45 Most were developed before the publication of PROM development and validation guidelines, chiefly the COSMIN methodology42,46,47 and US

Food and Drug Administration (FDA) guidelines,48 and the mainstream adoption of modern psychometric methods.49,50

We have developed the Patient-Reported Impact of Dermatological Diseases (PRIDD) measure in partnership with patients using both classic and modern psychometric methods. PRIDD captures the multidimensional impact of dermatological diseases on adult patients (≥ 18 years) using 16-items across four impact domains - physical, life responsibilities, psychological and social51 – and is for use in research and clinical practice. It has been developed through a rigorous, multi-year mixed methods process with 2,218 patients from 74 countries representing 95 dermatological conditions.3,29,43,51-54

Before a PROM can be recommended for use in research and clinical practice, validation of its measurement properties is required.55 PRIDD already has strong evidence of content validity, structural validity, internal consistency, acceptability and feasibility.3,51-53 Its remaining measurement properties - criterion validity, construct validity, test-retest reliability, measurement error and responsiveness – need to be evaluated.56,57 Interpretability information – floor and ceiling effects, score banding (categorisation of scores into clinically meaningful groups) and Minimally Important Change (MIC; smallest difference in scores that patients perceive as clinically meaningful or worthwhile)57 – is also needed to enhance practical utility and clinical relevance.

This final step in PRIDD's development and validation aims to i) test criterion validity, construct validity, test-retest reliability, measurement error and responsiveness and ii) examine floor and ceiling effects and determine the score bands and MIC.

Patients and methods

Study design and setting

We conducted a quantitative, longitudinal study consisting of two global online surveys administered two to four weeks apart. Ethical approval was obtained from Cardiff University School of Healthcare Sciences Ethics Committee (SREC:826). Informed consent was obtained from all participants.

Patients and recruitment

We used convenience sampling, recruiting participants through the International Alliance of Dermatology Patient Organizations' (GlobalSkin) network, a not-for-profit alliance of dermatology patient organisations worldwide (https://globalskin.org/). Consistent with best practices, PRIDD is being validated in English initially with later cross-cultural translation, following this study. Participants met the inclusion criteria if they were an adult (≥ 18 years),

self-reported a physician-diagnosis of a dermatological condition, and spoke English sufficiently to participate independently. Only those who participated in Survey 1, provided the mandatory demographic information (age, gender, and dermatological condition), and had ≤ 40% missing data were eligible to participate in Survey 2. COSMIN provides sample size requirements for each measurement property analysis.58 Of those tested here, the minimum sample sizes ranged from 50 to 100. Non-response determined non-participation.

Procedure and materials

Survey 1 was open from 29 June to 29 July 2022; Survey 2 from 12 July to 9 September 2022. Participants were directed to the online platform, developed by information technologists, which included the information sheet, consent form, and survey. Participants were given at least four weeks to respond with a reminder to participate email two weeks after to complete Survey 1 and/or two weeks after the Survey 1 invitation was sent, if it had not been completed.

Both surveys consisted of a battery of PROMs. The characteristics of these can be found in Table 1); Survey 1 included a brief demographics questionnaire (Appendix S1). Cronbach's α was calculated for each PROM.

Studies using the Global Perceived Effect scale (GPE) have used different definitions of 'minimal importance'. The decision about MIC is often taken by researchers based on the category they define as minimally important (e.g. 'much improved').59 As PRIDD emphasises the patient perspective, the cut-off point was determined by patients using the following item in Survey 2 (Appendix S2):

Which phrase below captures the smallest amount of change you consider to be a meaningful reduction in the impact of your dermatological condition on your life?

Completely improved

Much improved

Slightly improved

Patient involvement

GlobalSkin conceived of the PRIDD measure, were involved in setting the research priorities and defining research questions, and provided input into study design, conduct, and dissemination. Our lead patient co-researchers JA and AF are named co-authors.

Data analysis strategy

Data were analysed using SPSS v27. Descriptive statistics (frequencies and percentages) were produced to summarise the sample and data. Continuous data were summarised using the mean and standard deviation (SD) and range. Ordinal data were summarised using the median and interquartile.

The percentage of missing scores was examined for each PRIDD item. Distributions of item scores were examined using item means ($\bar{x}$) and standard deviations (SDs). Little's chi-squared test60 showed data were Missing Completely at Random (MCAR) at Survey 1, $p = 1$ but not at Survey 2, $p < 0.001$. Survey 2 missing values were replaced following the Expected Maximization method. Listwise deletion was used.

The significance level was set at $\alpha = 0.05$ for all tests, unless stated otherwise. All Spearman's ρ correlations were interpreted according to Table S1.61

Measurement properties

We followed the order of data analysis set out by COSMIN and evaluated the results against their quality criteria.59,62 Criterion and construct validity, floor and ceiling effects and score banding tests used Survey 1 data. All other measurement properties and the MIC used Survey 2 data. Structural validity and internal consistency results reported, including Person-Item Location Distribution Maps, derived from confirmatory factor analyses and Rasch measurement theory (RMT) analyses conducted during a previous PRIDD development study.51

Criterion validity

There is no gold standard PROM for the impact of dermatological disease,57 however, given the ubiquity of the Dermatology Life Quality Index (DLQI), we tested criterion validity against the DLQI. A Spearman's $\rho > 0.7$ between PRIDD and DQLI indicated sufficient criterion validity.62

Construct validity

Convergent validity consists of convergent (comparison with other outcome measurement instruments) and discriminative or known-groups validity (comparison between subgroups).46 We assessed convergent validity by testing 14 a priori hypotheses on the relationship between PRIDD and other PROMs using Spearman's ρ (Table S2). The statistical significance of correlations was not considered.59 We tested three a priori hypotheses to evaluate discriminative validity (Table S3) using independent-samples t-tests. The significance level was determined using a Bonferroni-corrected α of $0.05/3 = 0.016$. The number of hypotheses accepted and rejected was counted. Construct,

convergent, and discriminative validity were considered sufficient if ≥75% of the corresponding hypotheses were accepted, respectively.46

Test-retest reliability

An intraclass correlation coefficient (ICC) following the two-way random effects model46,59 was calculated between PRIDD scores at Survey 1 and Survey 2. ICCs were interpreted according to Table S4 with a coefficient of ≥ 0.70 indicating sufficient reliability. Only participants who responded 'no change' to the GPE were included.

Measurement error

We calculated (see Appendix S3) the Standard Error of Measurement (SEM), Smallest Detectable Change (SDC), Limits of Agreement (LoA), and two distribution-based (effect size and half standard deviation of PRIDD scores at Survey 1) and anchor-based MIC values (see below). Measurement error was acceptable if the SDC or LoA was lower than the MIC.46 Only participants who responded 'no change' to the GPE were included.

Responsiveness

We tested five a priori hypotheses to assess responsiveness (Table S5). A hypothesis was met if it reached the direction and magnitude hypothesised; statistical significance was not considered.59 The number of hypothesises accepted and rejected was counted. Responsiveness was sufficient if ≥75% of the hypotheses were accepted.46

Interpretability

Floor and ceiling effects

Floor or ceiling effects were considered present when > 15% of the patients achieved the minimum or maximum possible score62,63 and through visual inspection of the Person-Item Location Distribution Map, with respondents being below and above the range of measurement captured indicating floor and ceiling effects, respectively.

Score banding

Spearman's ρ correlations were used to examine the association between PRIDD scores with Patient Global Assessment of impact (PtGA-i) scores with ≥ 0.4 indicating that the PtGA-i was an acceptable patient-based anchor.64,65 We used mean, mode and median PtGA-i scores to assign five impact categories to PRIDD scores: no, mild, moderate, severe, and very severe impact. The weighted kappa coefficient of agreement (κ) was calculated for each set of potential bands and the banding option with the highest κ value was selected. κ coefficients were interpreted according to Table S6.66 The score banding sets identified were retested using the Survey 2 data by calculating the κ coefficient.

MIC

The MIC of PROMs should be considered from the perspective of the patient.59 We used the GPE as a patient-based anchor. Pearson correlations were used to establish the association between PRIDD change scores and the GPE with $\rho \geq 0.3$ indicating that the GPE was an acceptable anchor.67 In line with the FDA,68 we considered the interpretability of the change thresholds for both raw and transformed PRIDD scores, using two approaches - the mean change method59 and the visual anchor-based MIC distribution method69 - and compared the MIC values against the SDC.

Results

874 people registered to the online survey platform (Figure 1). Of these, 504 were eligible for inclusion in Survey 1 and 271 (53.77%) in Survey 2. Demographic data are provided in Table 2. The mean age was 56.11 (SD = 15) and most were female (79.2%) and White (79.1%). Thirty-five primary dermatological conditions and 38 countries were represented (Table 3). Cronbach's α for the scales was acceptable, ranging from 0.72 to 0.96 (Table S7).70 The majority of participants (95%) completed Survey 1 and 2 within a two to four interval; the remaining 14 (5%) within a four to ten-week interval. The non-response analysis revealed significant differences in ethnicity, WHO region and PNQ scores (see Appendix S4).

Descriptive statistics of the scores for each PROM are shown in Table 4. The percentage of missing values across the items was small, ranging from to 0% to 3.3% (Table S8).

Measurement properties

Criterion validity

Criterion validity was sufficient as there was a moderate to high correlation between PRIDD and DLQI scores, $\rho = 0.79$.

Construct validity

Convergent validity was sufficient as 11/14 (78.57%) hypotheses were met (Appendix S5). Discriminative validity was insufficient as only 2/3 (66.66%) hypotheses were met. Overall, 13/17 (76.47%) hypotheses were met and, therefore, construct validity was achieved.

Test-retest reliability

161 (59.41%) participants responded 'no change' on the GPE. Test-retest reliability was sufficient for all scales as all ICCs ≥ 0.70 (Table S9). The ICC value of 0.93 indicates that PRIDD is appropriate for use with both individuals and groups.70

Measurement error

Measurement error was sufficient as LoAs < MIC (Table S10).

Responsiveness

Participants were classified into six groups based on their responses to the GPE (Table S11). Due to the small sample sizes of some GPE groups, we collapsed the GPE into three groups - worse ('much worse' and 'slightly worse'), no change ('no change'), and improved ('slightly improved', 'much improved', and 'completely improved'). There was no difference in the overall results of the ANOVA, therefore, the original responses were used. Responsiveness hypothesis 1 was not met as there were no statistically significant differences in PRIDD total change scores between the different GPE groups, $F(5, 219) = 0.57$, $p = 0.72$.

All correlation coefficients for responsiveness hypotheses 2 to 6 were negligible and, therefore, were not supported (Table S12). Overall, responsiveness was insufficient as no hypotheses were met.

Interpretability

Floor and ceiling effects

The Person-Item Location Distribution Maps of PRIDD total and subscales showed that some respondents were above and below the range of measurement captured within the scale, indicating floor and ceiling effects (Figure S1).51 However, less than 15% of participants achieved the minimum or maximum PRIDD scores at both Survey 1 and Survey 2 (Table S13), indicating that these were within acceptable levels.

Score banding

PRIDD total and subscales scores were moderately to very highly correlated with the PtGA-i at Survey 1 and 2 (Table S14). For each score of PRIDD and the subscales, the number of patients with that score and their corresponding mode, mean, and median PtGA-i score is shown in Table S15. These, along with Figures S2-6, were used as the basis for grouping the PRIDD scores together into a set of five discrete bands. The bands with the highest

coefficient for each scale are presented in Table S16 and represent the final score bandings.

PRIDD total (0 - 63) and subscale scores are obtained in a two-step process by summing item scores and transforming these raw, ordinal level scores to interval level data using a conversion table (see Appendix S6).51 We recommend using the transformed rather than the raw scores but recognise that the latter may be more feasible in routine practice. As PRIDD scores operate at the interval level, the score bandings provided in Table 5 and Table S16 cover the whole range of PRIDD scores as there are no scores between those provided (i.e. no scores between 14.01 and 15.04, for example). The bandings using the raw, ordinal scores are also provided.

Table S17 shows that for all but Life Responsibilities Impact, the set of bands with the highest κ coefficient in Survey 2 matched Survey 1. Given the small sample size of Survey 2 and minor difference between the highest κ values for Life Responsibilities Impact, we retained the Survey 1 score banding.

MIC

As the GPE was not an acceptable anchor, ρ = 0.1, we could not calculate the anchor-based MIC.

Summary

A summary of PRIDD total's measurement properties and interpretability information evaluated against the COSMIN quality criteria is presented in Table 5. The subscales are summarised in Table S18.

Discussion

This study establishes evidence of PRIDD's construct validity, test-retest reliability, and measurement error and provides evidence-based score bandings to aid clinical interpretation.

Despite the need for the best evidence-based measures, those that fall short of the scientific standards remain in widespread use.71,72 To date, PRIDD is the only dermatology-specific PROM that can be recommended for use according to the COSMIN criteria (Table 5).42-45

Strengths and limitations

PRIDD is the first theory-led dermatology-specific PROM tested across all seven COSMIN measurement properties.43 This study met the highest COSMIN standards for tests of construct validity, test-retest reliability, and measurement error (Table S19).73

We recruited a diverse, international sample, however, as participants were primarily recruited through patient organisations, they may not be representative of the broader dermatology patient population. Despite a 46% attrition rate, the sample size remained sufficient for validation studies.74 A small number of participants (5%) completed Survey 2 more than 4 weeks after Survey 1 constraining the validity of the test-retest reliability, measurement error and responsiveness results. A non-responder analysis found significant difference between participant who did and did not respond to Survey 2 in ethnicity, WHO region and PNQ scores, potentially impacting the generalisability of the results. Though the GPE and PtGA-i are widely used they have not been validated for use with dermatology patients.

We were unable to determine PRIDD's MIC and responsiveness. The distribution-based MIC could not serve as a substitute as it does not incorporate the patient perspective.59,75 That said, while work to establish the anchor-based MIC is ongoing, we tentatively propose a MIC value of 4.14. As we followed COSMIN's recommendation to use a standardised, patient-based anchor, we have assumed that the issues encountered did not arise from the GPE anchor but rather from the study design. We initially chose a two to four week interval in line with PROM evaluation guidance.46,76 In hindsight, a one-month interval would have been more appropriate given PRIDD's one-month recall period; a shorter follow-up would not adequately capture the experiences and changes respondents had over the past month, potentially leading to incomplete or inaccurate assessments. Therefore, we recognise recall bias may have affected patients' responses. Third, insufficient cases across some GPE responses may have affected the precision of the results. Finally, PRIDD may not be responsive. Our ongoing study with a larger sample and a one-month interval aims to address these concerns and determine PRIDD's responsiveness and MIC.

Implications for clinical practice

NICE guidelines recommend a biopsychosocial approach to the management of dermatological conditions - measuring disease severity and the wider impact on the patient's life including physical, psychological, and social wellbeing. 27,77-79 PRIDD's subscales directly measure each of these impact domains. By providing clinicians with a more comprehensive understanding of patients' experiences, needs and concerns, PRIDD

can support patient-centred care, improve communication between patients and their clinical team, inform shared decision-making, guide patient self-management, and reveal high levels of psychological distress or physical symptoms that may require an immediate response (known as a PRO alert), allowing for rapid referral to appropriate specialist care.80,81

Through the stepped model of care, PROMs significantly impact treatment decision-making,82 influencing both the medications prescribed and the psychological support offered. For example, NICE guidelines specify a PASI score of ≥ 10 and DLQI > 10 before recommending apremilast to adult patients.83 This gatekeeping approach, where treatment access is contingent on meeting predetermined score thresholds, erroneously assumes the validity and reliability of dermatology PROMs.42-45 Even with patient involvement in PROM development, the final version may prioritise items more important to the developers than patients as they are rarely consulted during the item reduction process.43 This bias raises ethical concerns as powerful entities are shaping tools impacting less powerful individuals. To ensure the ethical use of PROMs in treatment decisions, there is a pressing need for them to genuinely capture what matters most to patients. Patients directly contributed to the prioritisation of PRIDD items.29,84 We have, therefore, produced a valid, reliable, acceptable and feasible tool53 that demonstrates what patients identify is important to consider within the stepped model of care. We provide score bandings but emphasise that these should be used to aid clinical interpretation and support and initiate rather than replace holistic discussions.

Implications for research

Core Outcome Sets (COSs) can advance dermatology by allowing us to systematically collate and compare findings from clinical trials and reduce selection bias.85-87 The CHORD COUSIN88 Collaboration (C3) focuses on COSs for trials and clinical practice in dermatology. Quality of life has been identified as a core outcome domain in COSs across several disease areas, but no existing PROMs can be recommended for use;89-91 PRIDD represents a promising candidate measure.

Dermatology-specific measures are often recommended or required by regulators as they can be used across the dermatology patient population and resultant data can be compared and collated.92,93 As with any dermatology-specific PROM, we recommend that PRIDD is used alongside, rather than instead of, disease-specific PROMs and intend to develop disease-specific additions to PRIDD.

This study validated the original, English-language version of PRIDD. It has since been translated into 16 other languages using best practice forward- and back-translation

methods with linguistic validation underway. Further studies are required to test PRIDD in different dermatology populations and settings. It will also be beneficial to revalidate PRIDD's measurement properties in a sample of patients not involved in the original development and validation.

Conclusion

PRIDD is a valid and reliable tool to help clinicians provide better care and stakeholders to understand the burden of dermatological disease. It is the first theory-led dermatology-specific PROM tested across all seven COSMIN measurement properties and the only one that can be recommended for use according to the COSMIN criteria. The results confirm the value of developing and validating PROMs with a patient-centred approach and using modern psychometric methods. The next steps include further testing of measurement error and responsiveness, linguistic validation, and collecting global data on the burden of dermatological conditions.

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Figure Legends

Figure 1: Study recruitment flowchart

1 Table 1: Summary of patient-reported outcome measures used

Measure	Construct of interest	Target population	Items (#)	Domains	Response options (item score)	Recall period	Score ranges	Score directions
Patient-Reported Impact of Dermatological Diseases (PRIDD)51	Impact of dermatological disease on the patient's life	Adults with a dermatological condition	16	4: Physical Impact, Life Responsibilities Impact, Psychological Impact, Social Impact	15 items - never (0), rarely (1), sometimes (2), often (3), always (4) One item - never (0), occasionally (1), often (2), always (3	1 month	Total score: 0 – 63; Physical Impact: 0 – 16; Life Responsibilities Impact: 0 – 19; Psychological Impact: 0 – 12; Social Impact: 0 - 16	Higher scores correspond to larger burden of disease
Dermatology Life Quality Index (DLQI)21	Quality of life	Adults with a dermatological condition	10	6: Symptoms and feelings, Daily activity, Leisure, Work and school, Personal	Very much (3), a lot (2), a little (1), not at all (0), not relevant (0)	1 week	Total score: 0 – 30; Symptoms and feelings: 0 – 6; Daily activity: 0 – 6; Leisure: 0 – 6; Work and	Higher scores correspond to a larger impact on quality of life and can interpreted

				relationships, Treatment			school: 0 – 3; Personal relationships: 0 – 6; Treatment: 0 - 3	as no impairment (0–1), mild impairment (2–5), moderate (6–10), severe (11–20) or very severe impairment to quality of life (21–30).94
Hospital Anxiety and Depression Scale (HADS)95	Anxiety and depression	Adults with physical health conditions	14	2: Anxiety (HADS-A), Depression (HADS-D)		1 week	HADS-A: 0 - 2896,97 HADS-D: 0 - 28	Higher scores indicating greater likelihood of the presence of anxiety or depression

Patient Needs Questionnaire (PNQ)20	Importance of treatment benefits	Adults with a dermatological condition	25	5: Reducing social impairments, Reducing psychological impairments, Reducing impairments due to therapy, Reducing physical impairments, Having confidence in healing98	Not a lot (0), somewhat (1), moderately (2), quite (3), very (4), does not apply to me (0)	1 day	Total score: 0 – 100; Reducing social impairments: 0 – 24; Reducing psychological impairments: 0 – 20; Reducing impairments due to therapy: 0 – 16; Reducing physical impairments: 0 – 20; Having confidence in healing: 0 - 1299	Higher scores indicating greater importance for treatment
Patient Global Assessment of impact (PtGA-i) 100	Patient's global assessment of the impact	Adults with physical health conditions	1		None at all (0), only a little amount (1), a moderate	1 month	0 - 4	Higher scores correspond to greater impact

	of their disease				amount (2), a large amount (3), a very large amount (4)			
Patient Global Assessment of severity (PtGA-s)100	Patient's global assessment of the severity of their disease	Adults with physical health conditions	1		Clear (0), mild (1), moderate (2), severe (3), very severe (4)	1 month	0 - 4	Higher scores correspond to greater severity
Global Perceived Effect (GPE)	Condition improvement or deterioration	Adults with physical health conditions	1		Completely improved (3), much improved (2), slightly improved (1), no change (0), slightly worse (-1), much worse (-2)	Since Survey 1 (approx. 2 - 4 weeks)		Higher positive scores correspond to greater improvement. Lower negative scores correspond to greater deterioration.

1

1 Table 2: Sample characteristics

	Survey 1, n (%)	Survey 2, n (%)
Total	504	271
Age	M = 56.11 (SD = 15; range = 18 to 92)	M = 56.74 (SD = 13.83; range = 23 to 83)
Years lived with condition	M = 14.44 (SD = 15.81; range = 0 to72)	M = 16.19 (SD = 17.29; range = 0 to 70)
Gender		
Male	100 (19.8)	43 (15.9)
Female	399 (79.2)	227 (83.7)
Other*	2 (0.4)	1 (0.4)
Ethnicity		
Black	11 (2.2)	6 (2.2)
East Asian	20 (4)	7 (2.6)
Latino	21 (4.2)	11 (4.1)
Middle Eastern	11 (2.2)	4 (1.5)
Mixed race	2 (0.4)	1 (0.4)
Oceana	2 (0.4)	1 (0.4)
South Asian	9 (1.8)	2 (0.7)

Southeast Asian	28 (5.6)	5 (1.9)
White	397 (79.1)	232 (85.9)
Other**	1 (0.2)	1 (0.4)
Native language		
English first language***	362 (73.9)	204 (77.3)
Highest qualification		
High school qualifications	100 (19.9)	55 (20.3)
A college or university diploma or degree	239 (47.5)	123 (45.4)
A higher degree or professional qualification (e.g. Doctorate or master's level degree)	160 (31.8)	93 (34.3)
None of these qualifications	4 (0.8)	0

M = mean

* Prefer to self-describe/Prefer not to say

**Description not provided

***Afrikaans, Arabic, Azerbaijani, Bulgarian, Cantonese, Cebuano, Chinese, Croatian, Czech, Danish, Dutch, Filipino, Finnish, French, German, Greek, Hindi, Italian, Japanese, Marathi, Norwegian, Portuguese, Romanian, Russian, Sinhalese, Spanish, Swedish, Tagalog, Telugu, Turkish, Urdu, Vietnamese

1

Table 3: Dermatological conditions and countries represented according to World Health Organization region

Dermatological condition	Survey 1, n (%)	Survey 2, n (%)
Albinism	3 (0.6)	1 (0.4)
Atopic dermatitis	33 (6.5)	16 (5.9)
Autoimmune skin diseases	5 (1)	4 (1.5)
Bullous Pemphigoid	49 (9.7)	26 (9.6)
Cutaneous Lymphomas	10 (2)	7 (2.6)
Cutis Laxa	3 (0.6)	3 (1.1)
Dyshidrotic Eczema	2 (0.4)	2 (0.7)
Epidermolysis Bullosa	3 (0.6)	2 (0.7)
Hidradenitis Suppurativa	14 (2.8)	10 (3.7)
Ichthyoses	6 (1.2)	4 (1.5)
Lichen Sclerosus	80 (15.9)	52 (19.2)
Lupus Erythematosus	4 (0.8)	3 (1.1)
Mucous Membrane Pemphigoid (Cicatricial Pemphigoid)	31 (6.2)	16 (5.9)
Mycosis Fungoides	3 (0.6)	2 (0.7)
Pachyonychia Congenita	12 (2.4)	7 (2.6)
Pemphigoid	19 (3.8)	10 (3.7)
Pemphigus Foliaceus	15 (3)	8 (3)
Pemphigus Superficial	2 (0.4)	1 (0.4)
Pemphigus Vulgaris	91 (18.1)	44 (16.2)
Psoriasis	75 (14.9)	29 (10.7)
Psoriasis Arthritis	10 (2)	5 (1.8)
Psoriatic Spondylitis	2 (0.4)	0

Topical Steroid Withdrawal Syndrome		21 (4.1)	13 (4.8)
Other*		11 (1.9)	6 (2.2)
Inflammatory condition		438 (86.9)	229 (84.5)
Countries			
WHO region	Countries represented		
African region	Algeria, South Africa	5 (1)	4 (1.5)
Region of the Americas	Argentina, Brazil, Canada, Colombia, Cuba, Mexico, USA	269 (55.5)	148 (56.5)
South-East Asian region	India, Philippines, Sri Lanka	21 (4.3)	4 (1.5)
European region	Belgium, Croatia, Czech Republic, Denmark, Finland, France, Germany, Ireland, Israel, Italy, Netherlands, Norway, Russia, Spain, Sweden, Switzerland, UK	119 (24.5)	76 (29)
Eastern Mediterranean region	Lebanon, Pakistan	2 (0.4)	1 (0.4)
Western Pacific	Australia, China, Hong Kong, Japan, New Zealand, Papua New Guinea, Vietnam	68 (14)	29 (11.1)

*Actinic Keratosis (Solar keratosis), Burning Mouth Syndrome, Corticosteroid Addiction Skin, Dermatitis Herpetiformis, Dermatitis Seborrheic, Hailey-Hailey disease, IGA Pemphigus, Lichen Planus, Ocular Cicatricial Pemphigoid, Rosacea, Sarcoidosis, Vitiligo (n=1); WHO: World Health Organization

Table 4: Patient-reported outcome measure descriptive statistics

	Survey 1		Survey 2	
Measure	Mean (SD)	Range	Mean (SD)	Range
PRIDD	29.38 (8.7)	0 to 63	27.42 (7.81)	0 to 47.59
Physical impact	8.38 (3.43)	0 to 16	7.61 (3.09)	0 to 16
Life Responsibilities impact	9.36 (3.95)	0 to 19	8.79 (3.77)	0 to 19
Psychological impact	5.89 (2.99)	0 to12	5.39 (2.87)	0 to 12
Social impact	6.47 (3.77)	0 to 16	5.81 (3.75)	0 to16
DLQI	9.31 (7.78)	0 to 30	8.85 (7.67)	0 to 30
Symptoms and feelings	2.45 (1.76)	0 to 6	2.32 (1.7)	0 to 6
Daily activities	2.02 (1.96)	0 to 6	2 (1.98)	0 to 6
Leisure	1.87 (2.05)	0 to 6	1.81 (2.05)	0 to 6
Work and school	0.63 (1.05)	0 to 3	0.17 (0.41)	0 to 2
Personal relationships	1.35 (1.76)	0 to 6	1.24 (1.7)	0 to 6
Treatment	0.97 (0.97)	0 to 3	0.96 (0.99)	0 to 3
PtGA-i	1.83 (1.13)	0 to 4	1.57 (1.1)	0 to 4
PtGA- s	1.78 (1.09)	0 to 4	1.64 (0.98)	0 to 4
HADS-A	7.5 (4.72)	0 to 21	-	-
HADS-D	5.66 (4.35)	0 to 21	-	-
PNQ	67.27 (23.24)	2 to 100	-	-
Social impairments	16.60 (6.51)	0 to 24	-	-
Psychological impairments	15.46 (4.81)	0 to 20	-	-
Impairments due to therapy	11.47 (4.39)	0 to 16	-	-

Physical impairments	16.55 (3.82)	1 to 20	-	-
Confidence in healing	9.92 (2.79)	0 to 12	-	-
GPE	-	-	3.24 (0.92)	1 to 6

DLQI; Dermatology Life Quality Index; GPE: Global Perceived Effect; HADS-A; Hospital Anxiety and Depression - Anxiety Subscale; HADS-D: Hospital Anxiety and Depression - Depression Subscale; PNQ: Patient Needs Questionnaire; PRIDD: Patient-Reported Impact of Dermatological Diseases PtGA-i: Patient Global Assessment of impact; PtGA-s: Patient Global Assessment of severity

Table 5: Summary of PRIDD total's measurement properties and interpretability information against the COSMIN quality criteria62

		Requirement	Rating	Results
Structural validity	Unidimensionality	- No violation of unidimensionality - No violation of local independence - Adequate model fit: $\chi 2$ >0.01	+	PRIDD and all subscales unidimensional with no local dependency. $\chi 2$ = 0.1151
	Structural validity	CFI or TLI or comparable measure > 0.95 OR RMSEA < 0.06 OR SRMR < 0.08	+	CFI = 0.96; TLI = 0.97; RMSEA = 0.09; SRMR = 0.0351
Internal consistency		- Person Separation Index ≥ 0.7 - Cronbach's α ≥ 0.7	+	Person Separation Index = 0.8951 α = 0.95
Hypothesis testing for construct validity		75% of hypotheses met	+	76% of hypotheses met
Test-retest reliability		ICC or weighted Kappa ≥ 0.70	+	ICC = 0.93
Measurement error		SDC or LoA < MIC	+	LoA (1.3) < MIC (4.14) Unable to determine anchor-based MIC
Responsiveness		The result is in accordance with the hypothesis OR AUC ≥ 0.70	-	0 hypotheses met
Floor & ceiling effects		Considered present when > 15% of the patients achieved the minimum or maximum possible score	+	< 0.9% with minimum or maximum score

MIC	N/A		4.14 (pending patient-perspective MIC)
Score banding	N/A		No impact: 0 to 14.01 (raw score 0 to 5); Mild impact: 15.04 to 25.73 (raw score 6 to 26); Moderate impact: 26.14 to 34.26 (raw score 27 to 44); Severe impact: 34.86 to 39.69 (raw score 45 to 52); Very severe impact: 40.53 to 63 (raw score 53 to 63)

"+" = sufficient, " –" = insufficient, "?" = indeterminate; α: Cronbach's alpha; CFI: Comparative Fit Index; ICC: Intraclass Correlation Coefficient; LoA: Limits of Agreement; MIC: Minimally Important Change; PSI: Person Separation Index; RMSEA: Root Mean Square Error of Approximation; SDC: Smallest Detectable Change; SRMR: Standardised Root Mean Square; TLI: Tucker-Lewis Index

1

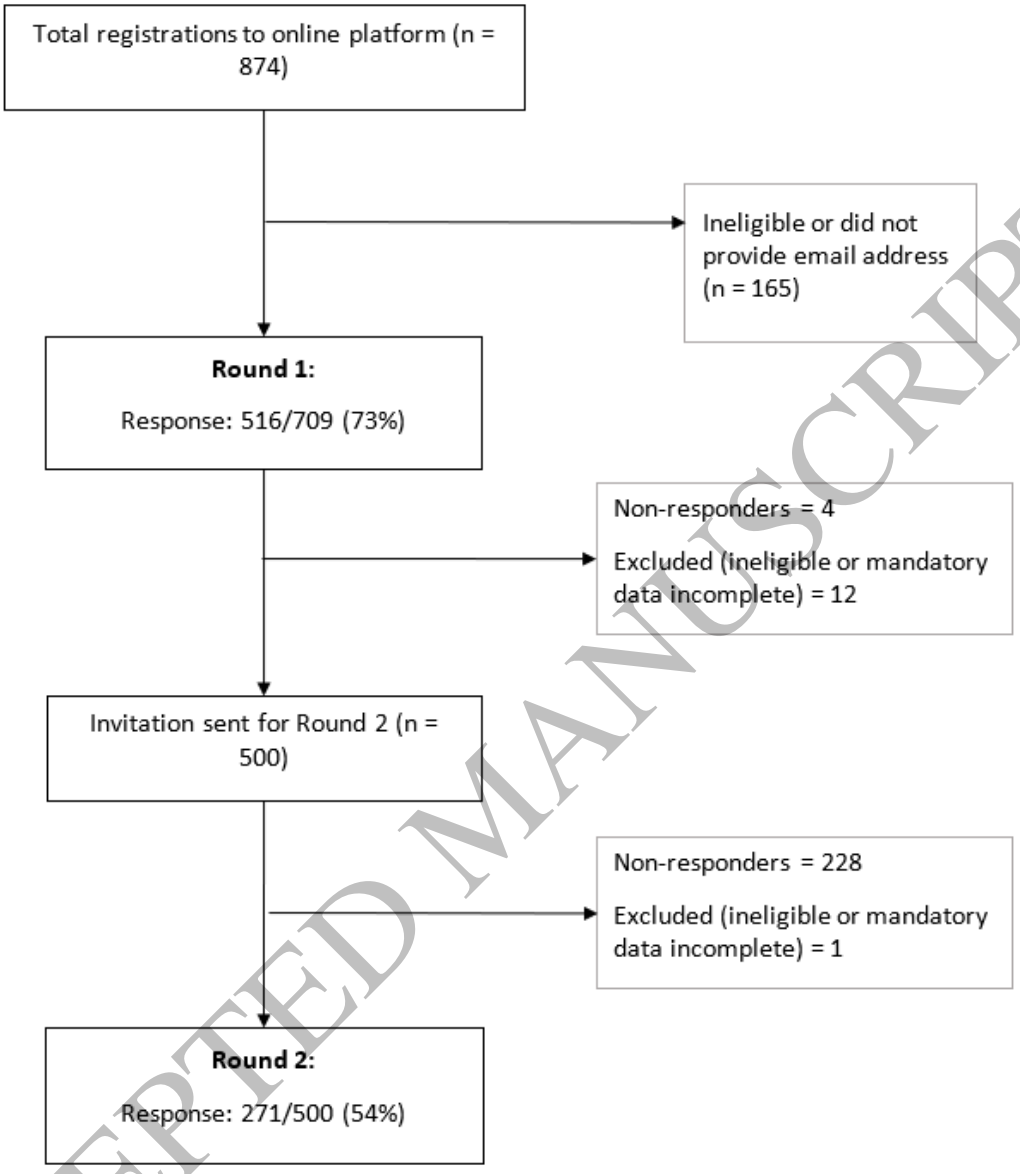

Figure 1
140x159 mm (x DPI)

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.

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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. 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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