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Are Welsh primary schools Sunproofed? Results of a national survey, part 1: scoping the landscape of sun safety policies in Wales

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Abstract

Background Schools with formal sun safety polices generally show better sun safety practices than schools without.

Objectives To understand the extent to which Welsh primary schools have sun safety policies; to identify the key characteristics of policies; to assess whether policy adoption varies by school characteristics; and to consider what support schools need to develop sun safety policies.

Methods An online multiple-choice survey on sun safety was distributed to all 1241 primary schools in Wales.

Results In total, 471 (38.0%) schools responded. Of these, 183 (39.0%) reported having a formal sun safety policy. Welsh medium schools ($P=0.036$) and schools in North Wales ($P=0.008$) were more likely to report having a policy. Schools with a higher percentage of pupils receiving free school meals ($P=0.046$) and with lower attendance rates ($P=0.008$) were less likely to report having a sun safety policy. The primary reasons for schools not having a policy included being 'not aware of the need' (34.6%); 'need assistance with policy or procedure development' (30.3%); and 'not got around to it just yet' (26.8%).

Conclusions With less than half of schools reporting a sun safety policy and variation in the presence/absence of a policy by school characteristics, our survey revealed inconsistency in formal sun safety provision in Welsh schools. The findings also suggest that schools are unaware of the importance of sun safety and need support to develop and implement policies. This snapshot of the current situation in primary schools in Wales provides a basis upon which the comprehensiveness, effectiveness and implementation of sun safety policies can be further evaluated.

What is already known about this topic?

- Despite skin cancer being one of the most preventable cancers, there is a 1 in 5 lifetime risk of developing the disease in the UK.
- Childhood is a critical time to avoid overexposure to the sun's ultraviolet rays – the major cause of skin cancer.
- Sun protection initiatives in primary schools can improve sun safe knowledge and behaviour.
- Schools with formal sun safety policies report more thorough sun safety practices.

What does this study add?

- Thirty-nine per cent of Welsh primary schools who responded to our survey had formal sun safety policies; 82% of these schools enforced them.
- Responding schools with more children receiving free school meals and with lower attendance records were less likely to have a sun safety policy.
- Responding schools without a sun safety policy were 'not aware of the need' (34.6%); 'need assistance with policy or procedure development' (30.3%); or 'not got around to it just yet' (26.8%).

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Although skin cancer is one of the most preventable forms of cancer with modified sun exposure,[1] in the UK, there is now a 1 in 5 lifetime risk of developing the disease.[2] With research evidence suggesting that children should take extra care in the sun to avoid future skin cancer,[3] teaching children how to protect themselves is one way to reduce future skin cancer rates.

Primary school-based sun safety education initiatives have been proven to increase sun protective knowledge and behaviours among children, with several systematic reviews proving their effectiveness.[4–6] Indeed, the World Health Organization suggests that school sun protection programmes may be the key to skin cancer prevention.[7] However, education initiatives may not be enough to ensure that behaviours are adopted, with evidence suggesting that schools with a written and formal sun protection policy have more thorough sun safety practices than those without.[8–10]

Very little research around sun safety in primary schools has been done in the UK, perhaps because of the maritime climate.[11,12] In Cornwall, few schools were found to have a formalized sun protection policy written into their staff manuals,[13] while a previous survey of 20 primary schools in Wales found that only 5 of the 13 responding schools (38%) had a sun safe policy in place.[14] Sun safety research in UK schools has typically focused on the adoption of specific guidelines or educational interventions,[15,16] and has not specifically addressed the presence or absence of a formal sun safety policy. In Wales, while it is recommended as part of the Welsh Network of Healthy Schools scheme that schools have a sun safety policy, unlike in England, there is no mandatory requirement to teach sun safety and there is no understanding of current practice.

To address this evidence gap, as part of the Sunproofed study we undertook a survey of all primary schools in Wales to understand if schools currently have formal sun safety policies, any defining characteristics of these policies, whether the adoption of a policy varied by area or school characteristic, and what support schools need in the area of policy development.[17]

Materials and methods

Study population

We used a database of all 1241 mainstream primary schools in Wales, according to My Local Schools,[18] a government-produced database with data on schools in Wales (data publicly available) based on data from the April 2021 census. This database contained school characteristics, including address, primary language (English or Welsh) and the percentage of children receiving free school meals. We obtained headteacher names and email addresses either from the 22 local authorities (LAs) responsible for education in Wales or via individual school websites.

Survey

Based on previous surveys conducted in South Wales and New Zealand,[14,19] we designed a brief online multiple-choice survey to ascertain whether schools had formal sun safety policies in place and to explore key aspects of sun safety (e.g. shade and suncream practices) in each school. The survey was tested extensively by our teacher and headteacher public involvement partners who made several suggestions to ensure that the survey was engaging, relevant and not too onerous for busy schools. Schools were given the option to complete the survey in English or Welsh.

We wrote to the Chief Education Officers or equivalent in each LA in Wales, introducing the survey and asking for their help in distribution. Seventeen of 22 LAs or the corresponding Healthy Schools coordinators agreed to send the survey out on our behalf. For the remaining five LAs, we emailed the survey to the headteacher of each school directly.

To coincide with the warmer weather in Wales, we opened the survey from June to September 2022. We included the Swansea University and funder logos on all our communications and offered respondents the opportunity be entered into a prize draw to win £500 of funds for their school, methods known to increase response rates.[20] We piloted the survey in two LAs and although no issues were identified with the survey questions themselves, the response rates were low. We therefore increased our incentive offer to complete the survey and offered all responding schools the opportunity to be entered into a draw to win £1000 for their school.

Nonresponding schools were sent up to three reminders, either directly from our study email address, from the LA or a mixture of both. In some cases, we found that surveys had not reached the headteacher either because the email address used was out of date or because the survey had remained unopened in an inbox. We therefore received ethical permission to call each school to verify the correct email address. Time and resource constraints prevented us from contacting each school; therefore, we concentrated on LAs where response rates were lower.

We translated all Welsh responses to English before analysis and included all pilot data in the final analysis. We grouped schools according to categories used by My Local Schools and StatsWales, for example the Welsh Education Consortium.[18,21] To estimate the number of pupils and full-time teachers at schools that had both a primary and secondary component, we assumed that there was an even distribution of pupils and teachers across school years and adjusted accordingly.

Analysis

To assess the extent to which our study cohort was representative of the overall population and to understand if specific characteristics were more prominent in schools with a sun safety policy, we expressed all categorical and continuous school characteristics as numbers (percentage, consistently reported to 1 decimal place) and interquartile ranges, respectively. We analysed data in STATA version 17.0 SE (StataCorp, College Station, TX, USA) according to a predefined analysis plan, using logistic regression analysis to calculate odds ratios (ORs) to summarize findings. We used $P < 0.05$ as statistically significant evidence against the null hypothesis of no difference between groups.

Table 1 shows the profile of the 1241 primary schools across Wales as detailed by My Local Schools,[18] with schools categorized according to geographical and school-based variables such as location and the Welsh Index of Multiple

Table 1 Key characteristics of the overall cohort of primary schools in Wales

Characteristics	Overall cohort ($n=1241$)
Welsh Education Consortium	
South West and Mid Wales	397 (32.0)
North Wales	340 (27.4)
Central South Wales	310 (25.0)
South East Wales	194 (15.6)
Welsh Index of Multiple Deprivation 2019 quintiles	
First quintile (most deprived)	223 (18.0)
Second quintile	255 (20.5)
Third quintile	286 (23.0)
Fourth quintile	295 (23.8)
Fifth quintile (least deprived)	182 (14.7)
Language ($n=1240$)[a]	
English	845 (68.1)
Welsh	395 (31.9)
Percentage of pupils receiving free school meals ($n=1112$)	18.6 (11.4–29.4)
Percentage of pupils of Black or minority ethnicity ($n=907$)	7.1 (4.3–14.7)
Total no. of pupils at the school ($n=1240$)	208 (115–305)
Pupil/teacher ratio ($n=1216$)	21.7 (19.3–23.8)
Attendance in 2019 ($n=1236$)	94.9 (94.0–95.5)
Full-time teachers ($n=1239$)	8.9 (5.3–13.3)

Data presented as *n* (%) or as median (interquartile range). [a]Data were incomplete for some characteristics.

Deprivation, an index designed to identify 'the small areas of Wales that are most deprived'.[22] The majority of schools in Wales teach in the medium of English ($n=845$; 68.1%).

Results

Response rates

In total, 471 schools returned our survey, an overall response rate of 38.0%. Response rates varied from 19.0% to 57.8% across LAs (see Figure 1), and were generally higher in areas where we had active engagement from the LA (e.g. where they sent or followed-up on the survey on our behalf).

Response rates also varied according to geographical region, with schools in North Wales more likely to have responded than South West and Mid Wales schools [OR 1.46, 95% confidence interval (CI) 1.09–1.97; $P=0.012$]. Schools with fewer full-time teachers were also more likely to have returned a survey (OR 0.98, 95% CI 0.97–1.00; $P=0.012$). For all other characteristics, the profile of responding schools generally matched those of schools that had not responded (Table 2).

Of the 462 schools that answered the question regarding who completed the survey, the majority of responses were provided by headteachers ($n=309$; 66.9%), followed

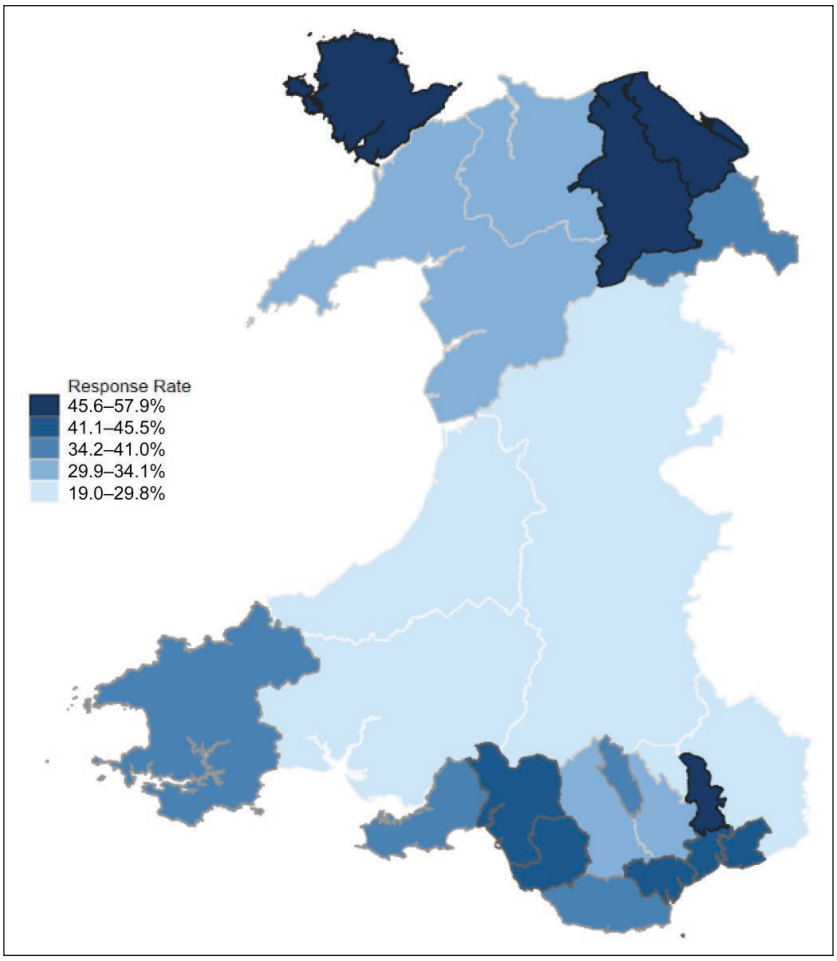

Figure 1 Map of survey response rates by Welsh Local Authorities.

Table 2 Key characteristics of responding schools ($n=471/1241$; 38.0%)

Characteristics	Returned survey	OR for returning a survey (95% CI)	*P*-value
Welsh Education Consortium			
South West and Mid Wales	137/397 (34.5)	Ref.	
North Wales	148/340 (43.5)	1.46 (1.09–1.97)	0.012
Central South Wales	121/310 (39.0)	1.22 (0.89–1.65)	0.215
South East Wales	65/194 (33.5)	0.96 (0.67–1.37)	0.809
Welsh Index of Multiple Deprivation 2019 quintiles			
First quintile (most deprived)	90/223 (40.4)	Ref.	
Second quintile	95/255 (37.3)	0.88 (0.61–1.27)	0.487
Third quintile	107/286 (37.4)	0.88 (0.62–1.26)	0.498
Fourth quintile	119/295 (40.3)	1.00 (0.70–1.42)	0.996
Fifth quintile (least deprived)	60/182 (33.0)	0.73 (0.48–1.09)	0.126
Language ($n=1240$)[a]			
English	327/845 (38.7)	Ref.	
Welsh	144/395 (36.5)	0.91 (0.71–1.16)	0.448
Percentage of pupils on free school meals ($n=1112$)	19.1 (12.2– 30.7)	1.01 (1.00–1.02)	0.117
Percentage of pupils who are of Black or minority ethnicity ($n=907$)	7.5 (4.3–17.7)	1.00 (1.00–1.01)	0.286
Total no. pupils at the school ($n=1240$)	202 (112–291)	1.00 (1.00–1.00)	0.053
Pupil/teacher ratio ($n=1216$)	21.7 (19.3–23.7)	1.01 (0.98–1.04)	0.580
Attendance 2019 ($n=1236$)	94.9 (94.0–95.6)	1.00 (0.92–1.10)	0.918
Full-time teachers ($n=1239$)	8.4 (5.0–12.7)	0.98 (0.96–1.00)	0.039

Data presented as *n* (%) or as median (interquartile range). CI, confidence interval; OR, odds ratio. [a]Data were incomplete for some characteristics.

by deputy headteachers ($n=40$; 8.7%) and administrators ($n=40$; 8.7%).

Sun safety policies

Of responding schools who answered the question 'Do you have a sun safety policy?', 39.0% ($n=183/469$) reported having a formal policy in place; however, of these 18.0% ($n=33$) did not currently enforce it. Just under half of responding schools ($n=231/469$; 49.3%) did not have a policy, while 11.7% ($n=55$) were unsure. Where policies existed, these were primarily based on resources provided by the LA ($n=76/181$; 42.0%), followed by Cancer Research UK ($n=47/181$; 26.0%) and the school's own

Table 3 School characteristics by sun safety policy presence or absence

Characteristics	Returned survey ($n=469$)[a]	Yes, school definitely has a sun safety policy ($n=183$; 39.0%)	No or unsure if school has a sun safety policy ($n=286$; 61.0%)	OR (95% CI)	*P*-value
Welsh Education Consortium ($n=469$)					
South West and Mid Wales	135 (28.8)	42 (31.1)	93 (68.9)	Ref.	
North Wales	148 (31.6)	69 (46.6)	79 (53.4)	1.93 (1.19–3.15)	0.008
Central South Wales	121 (25.8)	48 (39.7)	73 (60.3)	1.46 (0.87–2.44)	0.153
South East Wales	65 (13.9)	24 (36.9)	41 (63.1)	1.30 (0.70–2.41)	0.413
Welsh Index of Multiple Deprivation 2019 quintiles ($n=469$)					
First quintile (most deprived)	90 (19.2)	32 (35.6)	58 (64.4)	Ref.	
Second quintile	95 (20.3)	34 (35.8)	61 (64.2)	1.01 (0.55–1.84)	0.974
Third quintile	106 (22.6)	41 (38.7)	65 (61.3)	1.14 (0.64–2.05)	0.652
Fourth quintile	119 (25.4)	49 (41.2)	70 (58.8)	1.27 (0.72–2.23)	0.409
Fifth quintile (least deprived)	59 (12.6)	27 (45.8)	32 (54.2)	1.53 (0.78–2.99)	0.214
Language ($n=469$)					
English	326 (69.5)	117 (35.9)	209 (64.1)	Ref.	
Welsh	143 (30.5)	66 (46.2)	77 (53.8)	1.53 (1.03–2.28)	0.036
Percentage of pupils receiving free school meals ($n=419$)[b]	19.3 (12.2–30.8)	17.2 (11.0–27.7)	20.7 (12.7–31.8)	0.99 (0.97–1.00)	0.046
Percentage of pupils who are of Black or minority ethnicity ($n=339$)[b]	7.5 (4.3–18.0)	7.3 (3.9–15.1)	7.7 (4.7–19.4)	0.99 (0.98–1.01)	0.484
Total no. of pupils at the school ($n=469$)	202 (112–291)	196 (105–265)	207 (119–315)	1.00 (1.00–1.00)	0.134
Pupil/teacher ratio ($n=466$)	21.7 (19.3–23.6)	21.9 (19.5–24.0)	21.5 (19.1–23.5)	1.03 (0.98–1.09)	0.237
Attendance in 2019 ($n=469$)	94.9 (94.0–95.5)	95.1 (94.1–95.7)	94.7 (94.0–95.4)	1.25 (1.06–1.47)	0.008
Full-time teachers ($n=469$)	8.4 (5.0–12.7)	8.0 (4.8–11.0)	8.8 (5.8–13.8)	0.97 (0.94–1.00)	0.065

Data presented as *n* (%) or as median (interquartile range). CI, confidence interval; OR, odds ratio. [a]Two responding schools were excluded from this table as they did not answer whether they had a sun safety policy; [b]data were incomplete for some characteristics.

Table 4 Reasons for the lack of a sun safety policy

Reason	*n* (%)[a]
Not aware of the need	80 (34.6)
Need assistance with policy or procedure development	70 (30.3)
Not got around to it just yet	62 (26.8)
Lack of time to create a sun safety policy or procedure	48 (20.8)
Not a priority for school community at this time	30 (13.0)
Lack of resources to create a sun safety policy or procedure	29 (12.6)
Other	25 (10.8)
Would be too difficult to enforce	14 (6.1)
Do not see any advantages of creating a sun safety policy or procedure	13 (5.6)
Lack of resources to implement	12 (5.2)

[a]Multiple response questions were asked to the 231 schools that lack a sun safety policy; percentages may not total 100%.

research ($n=23/181$; 12.7%). Over a quarter of respondents ($n=50/181$; 27.6%) were unsure as to what their school's policy was informed by or based on.

School characteristics that influenced the presence or absence of a sun safety policy

The existence of a policy varied with respect to school characteristics. Schools in North Wales (OR 1.93, 95% CI 1.19–3.15; $P=0.008$) and Welsh medium schools (OR 1.53, 95% CI 1.03–2.28; $P=0.036$) were more likely to report having a sun safety policy. Those with a higher percentage of children receiving free school meals were less likely to report having a policy (OR 0.99, 95% CI 0.97–1.00; $P=0.046$), as were those with a lower attendance (OR 1.25, 95% CI 1.06–1.47; $P=0.008$) (Table 3).

Schools without a sun safety policy

We asked schools who did not have a sun safety policy to indicate the reasons why not. The most frequently chosen reasons were 'not aware of the need' ($n=80/231$; 34.6%), 'need assistance with policy or procedure development' ($n=70/231$; 30.3%) and 'not got around to it just yet' ($n=62/231$, 26.8%). Thirty schools (13.0%) said that a sun safety policy was 'not a priority for school community at this time' (Table 4).

When asked to indicate what would encourage their school to create a sun safety policy, the majority of schools ($n=165/226$; 73.0%) said assistance with policy development, followed by resources to aid the teaching of sun safety ($n=126/226$; 55.8%).

Discussion

Having a formal school policy that is communicated to the whole school community, sets out the position of the school and, when enforced properly, helps ensure all parties (governors, teachers, carers and children) are aware of their responsibilities when it comes to staying safe in the sun. Research evidence from other countries supports this – schools with a formal policy show stronger sun protective behaviours.[8–10] In Wales, our survey revealed that less than half (39.0%) of responding schools had a formal sun safety policy. Furthermore, the presence of a policy varied by school characteristics, suggesting a lack of consistency in this area across Wales. In particular – using free school meals as a proxy for deprivation in the school setting[23] – the finding that schools with a higher percentage of children receiving free school meals is concerning given that riskier sun safety behaviours have been shown in more deprived areas and in people from lower socioeconomic groups.[24,25] This finding suggests that pupils from these schools might be best placed to benefit from a formal policy, to help reduce future risky behaviour.

While 38.0% of primary schools in Wales responded to our survey, response rates varied across the country. Although we made every attempt to ensure a high response rate,[20] including taking advantage of record-breaking temperatures when sending out our survey,[26] >60% of schools did not reply. It is not possible to tell whether the survey invitation was overlooked (e.g. owing to the high number of emails schools receive) or whether sun safety is not a priority for nonresponding schools. While it is possible that schools with a policy were more inclined to respond, the finding that only 39% of respondents had a policy suggests that no participation bias was at play.[27] Although our response rate is much smaller than the 65% reported with a similar survey on a small sample of schools in South West Wales,[14] the proportion of schools completing the survey was similar across examined school characteristics in Wales, offering reassurance that the responding schools were representative of schools in the rest of the country.

As noted in the literature, strategies to improve sun safety policies need further study.[28,29] One limitation of the findings reported here is that we only investigated the presence or absence of a policy and not the comprehensiveness or effectiveness of any policy. Our next paper (part 2) will explore the relationship between the presence or absence of a school policy and a school's sun safety activities (manuscript in preparation). However, with regard to the findings reported herein, of concern is the fact that over a quarter of schools reported basing their policy on charity resources, including those from Cancer Research UK – resources that have not been updated for several years and are not readily available. Additionally, for any policy to be effective it must be actioned, and only 82.0% of responding schools with a policy reported enforcing it. Therefore, further research is needed to understand the barriers to implementation of existing policies and what can be done to address these issues.

The finding that 34.6% of respondents were unaware of the need for a sun safety policy is consistent with other studies that have reported a lack of awareness among school leaders.[30] This, combined with the finding that 26.8% of schools 'had not got around to it just yet' and 13.0% did not consider it a priority, suggests that there is work to be done in raising schools' awareness of the importance of sun safety education and provision. However, our survey has also highlighted that many schools in Wales feel that they do not have the time, resources or expertise to implement a sun safety policy. Encouragingly, despite these findings, schools that do not currently have a policy appear to be open to the idea, with 73.0% indicating they would welcome assistance with policy development.

Given the current lack of UK-based evidence in this area, using findings from Sunproofed we are holding a co-production event in which parents, teachers, headteachers, governors, Healthy Schools coordinators and other stakeholders in sun safety and skin cancer prevention will be invited to contribute to a simple set of sun safety guidelines.[17] These guidelines will be translated into Welsh and sent in both languages to all schools in Wales who can then adapt them to fit their local circumstances. It is our intention for future work to evaluate the effectiveness of these guidelines.

Despite skin cancer being largely preventable, there is still at least a 20% lifetime risk of developing the disease in the UK.[2] This is the first nationwide survey to explore the role of Welsh primary schools in helping to reverse this trend and reduce the burden on the National Health Service, with several important findings for policy and practice. With less than half of schools reporting the presence of a formal policy and variation in the presence or absence of a policy by school characteristic, findings show inconsistency in sun safety provision across Wales. Our results also suggest that there may be a greater need for sun safety support in schools in more deprived areas that have a higher percentage of children receiving free school meals.

With schools with no sun safety policy in place highlighting a lack of awareness, time and resource constraints, the findings of our study suggest that help is needed in this area. While this study did not address the comprehensiveness, effectiveness and implementation of sun safety policies, our next paper (part 2) will report on current sun safety practices and education in primary schools in Wales and explore the relationship between a school's activities and the presence or absence of a formal policy (manuscript in preparation). Herein, we have provided a snapshot of the current state of play in Wales from which to support schools if they are to both formally set out to protect children from the sun while at school and educate them on how to be safe in the sun to ultimately reduce their risk of future skin cancer.

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Conflicts of interest

The authors declare no conflicts of interest.

Data availability

Data are not publicly available. Please contact the corresponding author to discuss any requests.

Ethics statement

Ethical approval was received from Swansea University's Medical School Ethics Committee on 1 February 2022 (ref. 2021-0096).

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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. 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UK | 290802 | June 2023

Adverse Event Reporting:

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