1 Are Welsh primary schools Sunproofed? Results of a national survey Part 2: sun protection

- 2 practices in primary schools in Wales
- 3

Rachel A. Abbott,¹ Daniel Tod,² Kirsty Lanyon,² Timothy Driscoll,² Swetha Prathap,³ Alan Watkins² and
Julie Peconi²

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- ⁷ ¹Dermatology Department, Cardiff and Vale University Health Board, Cardiff, UK
- 8 ²Swansea Trials Unit, Faculty of Medicine, Health and Life Science, Swansea University, Swansea, UK
- 9 ³Blackpool Teaching Hospitals NHS Foundation Trust, Blackpool, UK
- 10
- 11 **Corresponding author:** Julie Peconi
- 12 Email: j.peconi@swansea.ac.uk
- 13
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22 What is already known about this topic?

- Skin cancers are common in the United Kingdom (UK), with at least a 1 in 5 lifetime risk, and they
 are mostly caused by ultraviolet radiation exposure
- The World Health Organisation recommends sun safety programmes in schools including
 - education, a supportive school environment, and a sun protection policy, as a cornerstone to skin cancer prevention strategies
 - However, sun safety programmes while encouraged, are not mandatory in schools in Wales
- 29 What does this study add?
- Only 29.0% of Welsh primary schools reported including sun protection education in the curriculum
 in every year group

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- Responding schools reported widespread variation in sun protection practices particularly around
 sunscreen application
- Schools with a formal sun safety policy were generally more likely to have stronger sun protection
 practices and sun safety education than schools without a policy
- 5

6 Abstract

- 7 Background. Skin cancer rates are on the rise globally. School sun safety programmes are recommended
- 8 by the World Health Organisation to reduce the risk of future skin cancer at population level; however,
- 9 these are encouraged but not mandated in Wales.
- Objectives. To explore current sun protection practices and sun safety education in primary schools in
 Wales and whether these are linked to the existence of a formal sun safety policy.
- Methods. An online survey to all 1241 Welsh primary schools asking about sun safety practices, education
 and formal policies.
- 14 Results. 471 (38.0%) schools responded with the profile of responding schools generally matching the profile of schools in Wales. A minority (22,4.7%) of responding schools reported they had sufficient shade 15 for most activities. In the spring and summer terms almost two thirds of schools encourage hat wearing 16 17 (304, 64.8%) and sunscreen (296, 63.2%). While nearly all schools reported that parents were encouraged 18 to apply sunscreen to students before school (449, 95.7%), there was wide variation in other sunscreen application practices. Less than one third of schools (129, 29.0%) reported that they include sun protection 19 education in the curriculum in every year group, with 11.7% (52) including this in certain years only. 20 Schools with a formal policy were more likely to report more comprehensive sun protection practices 21 including having sufficient shade [OR 1.51, 95% CI 1.04-2.19; p=0.032], having spare hats for pupils to 22 wear [OR 1.59, 95% CI 1.07-2.37; p=0.023], providing guidance for staff [OR 5.87, 95% CI 3.05-11.28; 23 p<0.001], encouraging them to model sun safe behaviours [OR 1.82, 95% CI 1.18-2.80; p=0.007] and 24
- teaching sun protection education as part of the curriculum in every year group [OR 2.56, 95% CI 1.763.71; p<0.001]. With respect to sunscreen, the existence of a formal policy did not seem to affect a school's
- 27 practice.
- Conclusions. While in most cases, the existence of a formal policy suggests more comprehensive sun
 protection practices and education in schools, sun protection measures and education need improvement
 across the primary school sector in Wales to reverse rising skin cancer rates.
- 31
- Wedi colli fy nhad i melanoma, ac fel rhywun sydd a chroen golau iawn (a'm plant), dwi'n 2ilch iawn i weld yr arolwg
 yma, a bod mwy o bwyslais ar ymwybyddiaeth o beryglon yr haul mewn ysgolion. Diolch.' Pennaeth, Ysgol ID24
- 34 'Lost my father to a melanoma, and as someone with very light skin (and my children), I'm very glad to see this
- 35 survey, and that there is more emphasis on awareness of dangers of the sun in schools. Thanks.' Headteacher,
- 36 School ID24

1 Background

2 Skin cancer (including both basal cell cancer and cutaneous squamous cell cancer - known collectively as keratinocyte cancer - and melanoma) is common in the United Kingdom (UK). There is a lifetime risk of 1 3 in 4 for men and 1 in 6 for women and the disease is increasing in incidence.^{1,2} It is estimated that around 4 50-90% of skin cancers are due to ultraviolet (UV) radiation exposure from the sun and are therefore 5 6 preventable through reduced sun exposure.³ Sun safety measures are recommended for children in the UK 7 between March and October when the UV index is ≥3 and these measures include seeking shade, using clothing to cover up, wearing broad-brimmed hats and using sunscreen.⁴ 8 9 10 Skin cancer prevention public health programmes in Australia have demonstrated strong economic benefits

for investment into skin cancer prevention.⁵ The World Health Organisation advises that appropriate school sun protection practices and sun safety education in childhood may reduce students' exposure to excessive UV radiation and ultimately reduce skin cancer risk.⁶ They argue that school approaches where possible, should include sun protection education, a supportive school environment including practices, a school endorsed sun protection policy and community and family involvement.⁶ Meanwhile, it is also important to recognise the role of sun exposure in vitamin D production and to ensure that children learn about the relative risks and benefits of sun exposure with respect to skin cancer and vitamin D deficiency.⁷

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In Wales, sun safety policies and educational activities are recommended as part of the Welsh Network of
Healthy Schools Schemes;⁸ however, they are not mandatory despite aligning with five of the strategic
priorities of Public Health Wales.⁹ Since 2021, in England, sun safety must now be included in the physical
health and wellbeing curriculum.¹⁰

With respect to formalising sun protection practices and education in primary schools, previous studies 23 24 from Australia have shown that schools that were part of the wider National SunSmart Schools program 25 showed more comprehensive sun protection practices including providing parents with sun protection information;¹¹ encouraging them to supply sunscreen to children;¹² and encouraging hat wearing as part of 26 27 the uniform.¹³ However, there is a paucity of research into skin cancer prevention in the UK, perhaps due to its rainfall and variable Atlantic climate.¹⁴ Evidence which does exist is now dated or small scale, for 28 example, in 1998, state schools in England were surveyed following the development of Sun Awareness 29 guidelines for Schools by the Department of Health, the Health Education Authority and British Association 30 31 of Dermatologists.¹⁵ Here, 804 (62%) primary school headteachers reported that they included aspects of sun awareness in their curriculum.¹⁵ However these Sun Awareness Guidelines are no longer made 32 available, and we do not know if they are still incorporated into education. In Cornwall in 2004, 54.2% of 33 34 227 schools responded to a survey of headteachers with 81.3% reporting that sun awareness was included 35 in the curriculum - with 97.3% reporting that it was included within pastoral care (personal, social and health education).¹⁶ More recently, twenty primary schools in South Wales were surveyed in 2009 about shade 36 provision, timing of outdoor breaks and sun protective clothing; however, this was part of a larger study.¹⁷ 37

2 education primary schools in Wales currently provide and whether this provision is linked to the existence

- 3 of a formal sun safety policy.
- 4

5 Method

We designed a brief, online multiple-choice survey based on previous surveys conducted in South Wales, 6 7 UK¹⁷ and New Zealand¹⁹, asking Head Teachers and Chair of Governors of schools about the presence or 8 absence of a formal sun safety policy and covering key sun protection practice and education areas. After 9 each question, respondents were able to record any free text comments. Please see supplementary file 1 for a copy of our school survey. We sent English and Welsh versions of the survey and up to three 10 11 reminders to all 1241 primary schools in Wales between June and September 2022. We translated all Welsh responses to English before analysis. Further details about our survey methodology are reported 12 elsewhere.20 13

14 Analysis

We analysed school-level data using Stata V17.0 SE according to a predefined analysis plan, using 15 16 generalised linear models to obtain adjusted comparisons of schools that have a formal sun safety policy 17 versus a combined group of schools that did not have a policy or were unsure. We adjusted for variables 18 which may impact the presence or absence of a policy, including: geographical indicators such as Welsh 19 education consortium (the geographical breakdown of schools used by StatsWales²¹); Welsh Index of 20 Multiple Deprivation (WIMD)²² guintile based on school postcode; and school characteristics from My Local Schools, a government produced database with data on schools in Wales,²³ including the primary 21 language of instruction (Welsh or English), the number of pupils and full-time teachers, pupil teacher ratio, 22 23 and average attendance rate at the school. For schools with both a primary and secondary component, we calculated an adjusted number of pupils and full-time teachers for the primary school section assuming that 24 school populations were evenly distributed across school years. 25

The precise form of model we used reflects the nature of the variable under consideration (logistic models for binary variables; ordinal logistic models for ordered variables; multinomial logistic models for nominal variables). We excluded responses of "other" and of "unsure" from analysis. For our primary analysis, we mostly omitted responses chosen by 5 or fewer schools, and responses categories with uncertainty in position within the ordinal scale. We conducted a sensitivity analysis exploring the impact of including responses that were excluded in the primary analysis.

We report survey responses as numbers and percentages alongside missingness and present comparisons as odds ratios (OR) with 95% confidence intervals and corresponding p-values. For ordinal logistic regression models, the reference category is indicated (coded as 1), with ORs interpreted accordingly. We regarded a p-value of less than 0.05 as statistically significant evidence to reject the null hypothesis of no difference between groups. Although we did not conduct a formal analysis of the optional free text comments, we include exemplars of common themes alongside our findings.

1 Results

2 We received survey responses from 471 (38.0%) primary schools in Wales, with responding schools generally matching the profile of schools across Wales.²⁰ Two schools did not answer the guestion about 3 whether they had a policy; we excluded them from analysis. Over one third of respondents (183, 39.0%) 4 reported the presence of a formal sun safety policy which primarily covered the following areas: sunscreen 5 6 guidelines (164, 89.6%), the wearing of hats (156, 85.2%), education e.g., how to enjoy the sun safely (137, 7 74.9%), and provision of shade at school (121, 66.1%). In addition to asking schools about sun safety policies, we asked them about key areas of sun safety and education, and present these findings below. 8 9 divided into school practices and resources, and pupil centred practices. Supplementary File 2 shows an

- 10 infographic of our key survey findings.
- 11 School practices and resources: shade, planning, communication, and staff education
- 12 Overall, the majority of schools (269, 57.4%) reported they had some useful shade but that it was
- 13 insufficient for most activities; whilst a small minority (22, 4.7%) had sufficient shade available for most
- 14 active pursuits (table 1). Over half of schools (258, 55.5%) had no plans to increase shade either because it
- 15 posed funding concerns (190, 40.9%) or was not a priority (68, 14.6%). Free text comments generally
- 16 reflected financial issues as illustrated by this Headteacher, 'despite us not having any outside shade at all
- 17 we have no available funding for the work to be done any time soon.' School ID371
- Schools with a formal sun safety policy were more likely to report having sufficient existing shade for active
 pursuits [OR 1.51, 95% Confidence Intervals (CI) 1.04-2.19; p=0.032] (table 1).
- With respect to planning 'education outside the classroom' activities, overall, the majority of schools (407, 94.2%) reported that they consider sun protection when planning activities with just over one third (169, 39.1%) reporting that this is formalised in a risk analysis (table 1). An informal approach to sun protection planning was also highlighted in free text comments, for example, *'There is no specific policy, but everyone uses common sense and avoids being out in the sun for a long period.'* – Headteacher, School ID24.
- When we explored schools based on policy status, schools with policies were more likely to include sun safety in a formal risk analysis [OR 2.15, 95% CI 1.43-3.21; p<0.001] and were also more likely to schedule outdoor activities whenever possible to minimise time outdoors between 10am and 3pm in the summer term or when the UV index is above 3 [OR 1.59, 95% CI 1.04- 2.42; p=0.032].
- With respect to communications, most schools (416, 94.5%), regardless of policy status, reported that they send out communications to parents regarding sun safety whilst over one third of schools (147, 37.7%) reported that they liaise with school governors regarding aspects of sun safety in school (table 1). Schools with a policy were more likely to liaise with governors regarding sun safety [OR 6.16, 95% CI 3.84-9.88; p<0.001].
- The majority of schools (277, 81.7%) reported that their staff manual did not contain guidance for staff regarding sun awareness issues (table 1); although schools with a policy were more likely to include this

2 model sun safe behaviours [OR 1.82, 95% CI 1.18-2.80; p=0.007].

3 Pupil-centred practices: education, sunscreen, uniform

Overall, 129 (29.0%) schools reported that they included sun protection in the curriculum in every year
group, while 52 (11.7%) included it in the curriculum in certain years only (table 2). Less than a quarter of
schools (98, 23.1%), reported teaching children about the sun as a source of vitamin D. When we explored
the impact of policy status, schools with a policy were both more likely to include sun protection in the
curriculum in every year group [OR 2.56, 95% CI 1.76-3.71; p<0.001] and teach about vitamin D [OR 2.70,
95% CI 1.65-4.42; p<0.001].

- 10 Regarding sunscreen, almost two thirds of all schools (296, 63.2%) advised application of sunscreen in the 11 spring and summer terms, with the vast majority (449, 95.7%) encouraging parents to apply it to their 12 children before school. Teacher involvement in sunscreen application varied greatly across schools, with 13 some schools requiring parent consent for teachers to help (115, 24.5%), some schools allowing teachers
- 14 to help with no parental consent required (87,18.6%) and others reporting that teachers were not allowed to
- 15 help at all (71,15.1%) (table 2). Under 10% (36, 7.7%) of schools did not have any stated guidelines around
- 16 sunscreen application. For example, 'Local Authority says that parents apply sunscreen before school for
- 17 the day and staff do not reapply. I think that this needs to change as children often sweat and need
- 18 sunscreen reapplied during the day.' Headteacher, School ID175
- 19 In most instances, the presence of a formal policy did not appear to affect sunscreen practices although
- schools with a policy were less likely to report not having guidelines concerning sunscreen application [OR
 0.32, 95% CI 0.13-0.79; p=0.013]. Free text comments highlighted confusion over who should apply
- 22 sunscreen and how often.

With respect to hat wearing, the majority of schools (304, 64.8%) reported that wearing hats, e.g a hat with 23 a brim or legionnaire cap, is encouraged in the spring and summer months. However, only 39 (8.3%) 24 reported that hats are part of the school uniform (table 2). A sensitivity analysis including categories 25 excluded from the ordinal logistic model, showed no change. Free text comments highlighted the difficulties 26 27 with hat wearing in schools as despite staff encouragement, it is often the younger children who mostly 28 wear hats: 'It is encouraged and most Foundation Phase children bring/wear a hat. Very few Key Stage 2 pupils bring/wear a hat.' - Headteacher, School ID300. A school's policy status also appeared to impact hat 29 wearing with schools with a policy more likely to report that children could borrow a spare hat if they forgot 30 their own [OR 1.59, 95% CI 1.07- 2.37; p=0.023]. 31

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33 Discussion

34 Summary of key findings of sun protection practices

35 Overall, findings show that sun safety practices and education vary greatly in primary schools across the 36 country, see Supplementary File #2. In particular, our survey has highlighted discrepancies and confusion

- 1 around sunscreen application and best practice. We also identified several areas where improvement is
- 2 needed including a lack of access to shade, discrepancies in sunscreen practices and uniform
- 3 requirements, and the omission of sun safety education in the curriculum for all year groups. While there
- 4 are no accepted UK benchmarks for what schools should be doing, given that sun safety measures such as
- 5 seeking shade, covering up with clothing and hats, and using sunscreen⁴ are all recommended for children
- 6 in the UK between March and October when the UV index is ≥3, our findings combined with rising skin
- 7 cancer rates² suggest improving sun safety practices and education in schools should be a priority.
- 8 Sun protection practices comparison with previous surveys in the UK and beyond
- Differences in the questions in the 2009 South Wales survey prevent comparison of sunscreen, shade and 9 10 behaviour; however, the proportion of schools reporting that they encourage pupils to wear hats has doubled from 31% in the 2009 survey¹⁷ to 65% in our survey. While these results appear promising, data 11 12 may not reflect a real change given the small sample of responding primary schools (n=13) in the previous survey. The higher number of schools reporting sun awareness in their curriculum in previous surveys: 62% 13 and 81% respectively in England generally (1998)¹⁵ and Cornwall specifically (2004)¹⁶ - compared with 38% 14 in our survey – may be explained by the timing soon after release of the Sun Awareness Guidelines, 15 differences in survey wording or perhaps by differences in the curricula of England and Wales. Given that 16 the guidelines explored in these studies are no longer publicly available and that sun safety education now 17 a mandatory part of the curriculum in England, it would be interesting to see how these findings have 18 changed over time. Unfortunately, the level of sun protection practices reported in our study differ 19 dramatically from those reported in New Zealand where the majority of schools either enforced (90%) or 20 encouraged (10%) hat wearing, 60% had sufficient shade for passive activities and 41% taught sun 21 protection as part of the curriculum in every year.²⁴ 22
- 23 Impact of formal school sun safety policy

24 We've shown that schools in Wales with a formal policy exhibit more comprehensive sun protection practices and education than those without. In particular, schools with a formal sun safety policy were more 25 likely to report having sufficient existing shade for most activities, include sun safety in a formal risk 26 analysis for education outside the classroom, communicate with governors regarding sun safety in school, 27 include sun safety in the curriculum in every year group and teach about vitamin D (as recommended by 28 29 NICE)⁷. In contrast, schools without a formal sun safety policy were more likely to report that sun safety was discussed in assembly as the need arose (i.e. not included in the curriculum) and were less likely to 30 provide guidance on sun awareness for staff. While the presence of a formal policy did not appear to 31 greatly influence practices towards sunscreen, as expected schools without a policy were less likely to have 32 33 any sunscreen specific guidelines. These schools were also less likely to have spare hats which pupils 34 could borrow. While we grouped schools with no policy with those who were unsure, if some of the unsure schools in actual fact do have a policy, this may underestimate the reported effects of a policy. 35

In our previous paper we showed that only 39% of responding schools reported a formal sun safety policy
 and that schools with a higher percentage of children on free school meals were less likely to report having
 a formal policy.²⁰ Given that the presence of a policy improves sun protection practices and education,

- 1 more work is urgently needed to address these findings, particularly in areas of deprivation where riskier
- 2 sun safe behaviours have been shown.²⁵
- 3 Strengths and Limitations

In Wales, while it is recommended as part of the Welsh Network of Healthy Schools Scheme that schools 4 5 have polices in place for sun safety, there are no central resources provided in this area. This is the first national survey, to which all comprehensive primary schools in Wales were invited to participate, looking at 6 sun safety policies and practices across Wales. We have provided evidence both on current sun safety 7 8 practices and education, and the role of a formal school sun safety policy in contributing to more comprehensive school actions in this area. While it was outside the scope of this study, our next proposed 9 study will evaluate the comprehensiveness, inclusiveness and implementation of school policies to identify 10 lessons for best practice across Wales. Although our response rate was low (38.0%), the responding 11 schools generally matched the profile of schools across Wales.²⁰ And finally, while we recognise that survey 12 respondents may have answered inaccurately to reflect perceived 'desirable behaviour'²⁶ this doesn't 13 appear to be the case here with respondents reporting several areas where sun safety provision and 14 education are lacking. 15 16

17 Conclusion

18 Learning about sun safety at primary school has the potential to kickstart lifelong healthy behaviours in the sun and ultimately reduce skin cancer risk and is recommended by the World Health Organisation.⁶ Our 19 results demonstrate that sun protection measures and education around sun safety vary greatly across 20 Wales and remain inadequate in many primary schools. While the existence of a formal sun safety policy 21 suggests more comprehensive sun safety practices and education in schools, in general, sun protection 22 measures and education need improvement in many primary schools in Wales. These data will be a 23 benchmark to assess the change in practices and sun safety policies in school moving forwards and will 24 help to inform the development of appropriate national primary school sun protection guidelines with the 25 aim of improving knowledge and behaviours around sun safety and vitamin D for children in Wales. 26

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- 3
- Table 1. Survey responses for school practices and resources: shade, planning, communication, education
 and staff

			N	
Question responses	Total n (%)	No or	Yes, the	OR [95%
	n = 469	unsure if	school	CI] (p-
		the school	DEFINITELY	value)
		has a sun	has a sun	
		policy	policy	
		n = 286	n = 183	
		(61.0%)	(39.0%)	
What is the current situation at your school with		de? Consider tr	ees, covered o	or sheltered
areas and portable shade (such as gazebos). ^a (n		r		Y
1= Inadequate shade for students to use for any	48 (10.2%)	32 (11.2%)	16 (8.7%)	1.51
activity				[1.04,
2= Some useful shade but insufficient for most	269 (57.4%)	173 (60.5%)	96 (52.5%)	2.19]
activities				(p=0.032)
3= Sufficient existing shade for most students	130 (27.7%)	69 (24.1%)	61 (33.3%)	
to sit under for passive activities either all at				
once or in shifts (e.g. eating lunch outdoor or				
classroom activities)				
4= Sufficient shade available for most active	22 (4.7%)	12 (4.2%)	10 (5.5%)	1
pursuits (e.g. shade cover over playground			, , , , , , , , , , , , , , , , , , ,	
activities)		7		
Does your school have future plans for increasin	g shade? ^b (n =	465, missing =	4)	
No plans to increase shade - our school already		16 (5.6%)	15 (8.3%)	(referenc
has sufficient shade		- (/	- ()	e
				category)
No definite plans to increase shade - as it poses	190 (40.9%)	113 (39.8%)	77 (42.5%)	0.60
funding concerns		(,	([0.27,
				1.34]
				(p=0.211)
No dofinito plans to increase shade as it is not				
NO DETUDE DIALS TO IDCLEASE SUBDE - AS ILLS NOT	68 (14 6%)	45 (15 8%)	23 (12 7%)	0 47
No definite plans to increase shade - as it is not a priority area	68 (14.6%)	45 (15.8%)	23 (12.7%)	0.47 [0.19
a priority area	68 (14.6%)	45 (15.8%)	23 (12.7%)	[0.19,
	68 (14.6%)	45 (15.8%)	23 (12.7%)	[0.19, 1.15]
a priority area				[0.19, 1.15] (p=0.098)
a priority area Definite plans to increase shade in the next 5	68 (14.6%) 99 (21.3%)	45 (15.8%) 62 (21.8%)	23 (12.7%) 37 (20.4%)	[0.19, 1.15] (p=0.098) 0.53
a priority area				[0.19, 1.15] (p=0.098) 0.53 [0.23,
a priority area Definite plans to increase shade in the next 5				[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25]
a priority area Definite plans to increase shade in the next 5 years	99 (21.3%)	62 (21.8%)	37 (20.4%)	[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25] (p=0.146)
a priority area Definite plans to increase shade in the next 5 years Definite plans to increase shade in the next 12				[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25] (p=0.146) 0.47
a priority area Definite plans to increase shade in the next 5 years	99 (21.3%)	62 (21.8%)	37 (20.4%)	[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25] (p=0.146) 0.47 [0.19,
a priority area Definite plans to increase shade in the next 5 years Definite plans to increase shade in the next 12	99 (21.3%)	62 (21.8%)	37 (20.4%)	[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25] (p=0.146) 0.47 [0.19, 1.18]
a priority area Definite plans to increase shade in the next 5 years Definite plans to increase shade in the next 12 months	99 (21.3%) 61 (13.1%)	62 (21.8%) 40 (14.1%)	37 (20.4%) 21 (11.6%)	[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25] (p=0.146) 0.47 [0.19, 1.18] (p=0.109)
a priority area Definite plans to increase shade in the next 5 years Definite plans to increase shade in the next 12 months Other ^d	99 (21.3%) 61 (13.1%) 16 (3.4%)	62 (21.8%) 40 (14.1%) 8 (2.8%)	37 (20.4%) 21 (11.6%) 8 (4.4%)	[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25] (p=0.146) 0.47 [0.19, 1.18] (p=0.109) n/a
a priority area Definite plans to increase shade in the next 5 years Definite plans to increase shade in the next 12 months Other ^d Is sun protection reflected in the planning of "ed	99 (21.3%) 61 (13.1%) 16 (3.4%) ucation outsid	62 (21.8%) 40 (14.1%) 8 (2.8%) e the classroor	37 (20.4%) 21 (11.6%) 8 (4.4%)	[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25] (p=0.146) 0.47 [0.19, 1.18] (p=0.109) n/a
a priority area Definite plans to increase shade in the next 5 years Definite plans to increase shade in the next 12 months Other ^d Is sun protection reflected in the planning of "ed the summer term? ^a (e.g. camps, excursions and	99 (21.3%) 61 (13.1%) 16 (3.4%) ucation outsid sporting event	62 (21.8%) 40 (14.1%) 8 (2.8%) e the classroor (s) (n = 432)	37 (20.4%) 21 (11.6%) 8 (4.4%) n" activities co	[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25] (p=0.146) 0.47 [0.19, 1.18] (p=0.109) n/a nducted in
a priority area Definite plans to increase shade in the next 5 years Definite plans to increase shade in the next 12 months Other ^d Is sun protection reflected in the planning of "ed the summer term? ^a (e.g. camps, excursions and 1= Not considered	99 (21.3%) 61 (13.1%) 16 (3.4%) ucation outsid sporting event 24 (5.6%)	62 (21.8%) 40 (14.1%) 8 (2.8%) e the classroor (n = 432) 17 (6.6%)	37 (20.4%) 21 (11.6%) 8 (4.4%) n" activities co 7 (4.0%)	[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25] (p=0.146) 0.47 [0.19, 1.18] (p=0.109) n/a nducted in
a priority area Definite plans to increase shade in the next 5 years Definite plans to increase shade in the next 12 months Other ^d Is sun protection reflected in the planning of "ed the summer term? ^a (e.g. camps, excursions and 1= Not considered 2= Yes, considered but not formalised in risk	99 (21.3%) 61 (13.1%) 16 (3.4%) ucation outsid sporting event	62 (21.8%) 40 (14.1%) 8 (2.8%) e the classroor (s) (n = 432)	37 (20.4%) 21 (11.6%) 8 (4.4%) n" activities co	[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25] (p=0.146) 0.47 [0.19, 1.18] (p=0.109) n/a mducted in
a priority area Definite plans to increase shade in the next 5 years Definite plans to increase shade in the next 12 months Other ^d Is sun protection reflected in the planning of "ed the summer term? ^a (e.g. camps, excursions and 1= Not considered	99 (21.3%) 61 (13.1%) 16 (3.4%) ucation outsid sporting event 24 (5.6%)	62 (21.8%) 40 (14.1%) 8 (2.8%) e the classroor (n = 432) 17 (6.6%)	37 (20.4%) 21 (11.6%) 8 (4.4%) n" activities co 7 (4.0%)	[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25] (p=0.146) 0.47 [0.19, 1.18] (p=0.109) n/a nducted in 2.15 [1.43, 3.21]
a priority area Definite plans to increase shade in the next 5 years Definite plans to increase shade in the next 12 months Other ^d Is sun protection reflected in the planning of "ed the summer term? ^a (e.g. camps, excursions and 1= Not considered 2= Yes, considered but not formalised in risk	99 (21.3%) 61 (13.1%) 16 (3.4%) ucation outsid sporting event 24 (5.6%)	62 (21.8%) 40 (14.1%) 8 (2.8%) e the classroor (n = 432) 17 (6.6%)	37 (20.4%) 21 (11.6%) 8 (4.4%) n" activities co 7 (4.0%)	[0.19, 1.15] (p=0.098) 0.53 [0.23, 1.25] (p=0.146) 0.47 [0.19, 1.18] (p=0.109) n/a mducted in

Unsure ^d	37	29	8	n/a
In the summer term or when the UV index is abov	· · ·			ne spent in
the sun by undertaking any of the following activ	rities? ^c (n = 404	1, missing = 65)		
Assemblies are held indoors, or if outdoors are	181 (44.8%)	98 (42.2%)	83 (48.3%)	1.38
held under shade or before 10am				[0.90,
				2.10]
				(p=0.135)
Teachers are requested to use shade for	136 (33.7%)	72 (31.0%)	64 (37.2%)	1.40
outdoor classes after 10am	()		- ()	[0.90,
				2.16]
				(p=0.132)
Outdoor activities, are scheduled, whenever	163 (40.3%)	83 (35.8%)	80 (46.5%)	(p=0.132) 1.59
	103 (40.378)	05 (55.070)	80 (40.378)	
possible, to minimise time outdoors between				[1.04,
10am and 3pm				2.42]
				(p=0.032)
Lunch is eaten indoors	271 (67.1%)	158 (68.1%)	113 (65.7%)	1.00
			X	[0.64,
				1.55]
				(p=0.995)
Lunch is eaten outdoors but in shady areas	100 (24.8%)	56 (24.1%)	44 (25.6%)	1.04
			•	[0.63,
				1.70]
				(p=0.884)
Children are allowed to stay indoors during	156 (38.6%)	85 (36.6%)	71 (41.3%)	1.24
breaks on sunny days			, ,	[0.81,
, ,				1.91]
				(p=0.322)
There is an extended morning and shortened 🦯	28 (6.9%)	15 (6.5%)	13 (7.6%)	1.20
lunch break	20 (0.570)	13 (0.370)	13 (7.070)	[0.53,
Iditeribreak	Y			[0.53 <i>,</i> 2.69]
				-
Other ^d	20 (5.0%)	12 (5 20/)	9(4,70/)	(p=0.666)
	20 (5.0%)	12 (5.2%)	8 (4.7%)	n/a
Does your school send out any communications t	to parents rega	arding sun safe	ty? (n = 440, n	nissing = 2)
No	24 (5.5%)	20 (7.7%)	4 (2.2%)	Referenc
				е
				-
Yes - please provide more information in the	416 (94,5%)	239 (92.3%)	177 (97.8%)	category
	416 (94.5%)	239 (92.3%)	177 (97.8%)	category 3.66
Yes - please provide more information in the comments box below	416 (94.5%)	239 (92.3%)	177 (97.8%)	category 3.66 [1.18,
	416 (94.5%)	239 (92.3%)	177 (97.8%)	category 3.66 [1.18, 11.33]
comments box below				category 3.66 [1.18, 11.33] (p=0.025)
	416 (94.5%) 27	239 (92.3%) 25	177 (97.8%) 2	category 3.66 [1.18, 11.33]
comments box below	27	25	2	category 3.66 [1.18, 11.33] (p=0.025) n/a
comments box below Unsure ^d	27	25	2	category 3.66 [1.18, 11.33] (p=0.025) n/a
comments box below Unsure ^d Does your school liaise with governors regarding	27	25	2	category 3.66 [1.18, 11.33] (p=0.025) n/a
comments box below Unsure ^d Does your school liaise with governors regarding a 1)	27 any aspects of	25 sun safety in so	2 chool? (n = 390	category 3.66 [1.18, 11.33] (p=0.025) n/a), missing =
comments box below Unsure ^d Does your school liaise with governors regarding a 1)	27 any aspects of	25 sun safety in so	2 chool? (n = 390	category 3.66 [1.18, 11.33] (p=0.025) n/a 0, missing = Referenc e
comments box below Unsure ^d Does your school liaise with governors regarding a 1) No	27 any aspects of 243 (62.3%)	25 sun safety in so 176 (79.3%)	2 chool? (n = 390 67 (39.9%)	category 3.66 [1.18, 11.33] (p=0.025) n/a), missing = Referenc e category
comments box below Unsure ^d Does your school liaise with governors regarding a 1) No	27 any aspects of	25 sun safety in so	2 chool? (n = 390	category 3.66 [1.18, 11.33] (p=0.025) n/a 0, missing = Referenc e category 6.16
comments box below Unsure ^d Does your school liaise with governors regarding a 1)	27 any aspects of 243 (62.3%)	25 sun safety in so 176 (79.3%)	2 chool? (n = 390 67 (39.9%)	category 3.66 [1.18, 11.33] (p=0.025) n/a 0, missing = Referenc e category 6.16 [3.84,
comments box below Unsure ^d Does your school liaise with governors regarding a 1) No	27 any aspects of 243 (62.3%)	25 sun safety in so 176 (79.3%)	2 chool? (n = 390 67 (39.9%)	category 3.66 [1.18, 11.33] (p=0.025) n/a), missing = Referenc e category 6.16 [3.84, 9.88]
comments box below Unsure ^d Does your school liaise with governors regarding a 1) No Yes	27 any aspects of 243 (62.3%) 147 (37.7%)	25 sun safety in so 176 (79.3%) 46 (20.7%)	2 chool? (n = 390 67 (39.9%) 101 (60.1%)	category 3.66 [1.18, 11.33] (p=0.025) n/a 0, missing = Referenc e category 6.16 [3.84, 9.88] (p<0.001)
comments box below Unsure ^d Does your school liaise with governors regarding a 1) No	27 any aspects of 243 (62.3%)	25 sun safety in so 176 (79.3%)	2 chool? (n = 390 67 (39.9%)	category 3.66 [1.18, 11.33] (p=0.025) n/a), missing = Referenc e category 6.16 [3.84, 9.88]
comments box below Unsure ^d Does your school liaise with governors regarding a 1) No Yes	27 any aspects of 243 (62.3%) 147 (37.7%) 78	25 sun safety in so 176 (79.3%) 46 (20.7%) 63	2 chool? (n = 390 67 (39.9%) 101 (60.1%) 15	category 3.66 [1.18, 11.33] (p=0.025) n/a 0, missing = Referenc e category 6.16 [3.84, 9.88] (p<0.001) n/a

No	277 (81.7%)	177 (91.7%)	100 (68.5%)	Referenc		
				е		
				category		
Yes	62 (18.3%)	16 (8.3%)	46 (31.5%)	5.87		
				[3.05,		
				11.28]		
				(p<0.001)		
Unsure ^d	125	91	34	n/a		
Are staff encouraged to model sun safe behaviours for students such as hat wearing? (n = 438, missing = 3)						
No	149 (34.0%)	102 (38.9%)	47 (26.7%)	Referenc		
				е		
				category		
Yes	289 (66.0%)	160 (61.1%)	129 (73.3%)	1.82		
				[1.18,		
				2.80]		
				-		
Unsure ^d				(p=0.007)		

^a Ordinal logistic regression – the outputs are alongside the responses that were included in the model. The

reference is the first category and ordered as in table.

3 ^b Multinomial logistic regression

4 ^c Multiple response question – n and percentages may not add up to the total or 100%

5 ^d Category excluded from regression analysis

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7 Table 2. Survey responses for pupil-centred practices: sunscreen, uniform

Question responses	Total n (%)	No or	Yes, the	OR [95% CI]	
Question responses	n = 469	unsure if	school	(p-value)	
	11 - 105	the school	DEFINITELY	(p value)	
		has a sun	has a sun		
		policy	policy		
		n = 286	n = 183		
A Y		(61.0%)	(39.0%)		
Does your school link sun protection to the curri	culum?ª (n = 44	l5, missing = 1)			
1= No, but discussed as the need arises (for	172 (38.7%)	123 (46.4%)	49 (27.2%)	2.56 [1.76,	
example during sunny spells)				3.71]	
2= No, but discussed in assembly	74 (16.6%)	45 (17.0%)	29 (16.1%)	(p<0.001)	
3= Yes, included as part of the curriculum in	52 (11.7%)	26 (9.8%)	26 (14.4%)		
certain year groups only					
4= Yes, included as part of the curriculum, in	129 (29.0%)	55 (20.8%)	74 (41.1%)		
every year group					
Sun protection is not taught ^c	10 (2.2%)	10 (3.8%)	0 (0.0%)	n/a	
Other ^c	8 (1.8%)	6 (2.3%)	2 (1.1%)	n/a	
Unsure ^c	23	21	2	n/a	
Which aspects of how to enjoy the sun safely does your school teach? ^b (n = 425, missing = 2)					
(Branching from above question, if "Yes" OR "No")					
Drinking plenty of fluid	419 (98.6%)	243 (98.4%)	176 (98.9%)	1.18 [0.19,	
				7.16]	
				(p=0.857)	

Wearing protective clothing including hat wearing	404 (95.1%)	233 (94.3%)	171 (96.1%)	1.49 [0.56, 3.94]
wearing				(p=0.424)
Wearing protective clothing including	244 (57.4%)	138 (55.9%)	106 (59.6%)	1.09 [0.73,
sunglasses	211 (37.170)	100 (00.070)	100 (00.070)	1.65]
54115145565				(p=0.665)
Using sunscreen	416 (97.9%)	241 (97.6%)	175 (98.3%)	1.57 [0.35,
	- (/	(- (/	6.99]
				(p=0.551)
Seeking shade	389 (91.5%)	223 (90.3%)	166 (93.3%)	1.63 [0.76,
			. ,	3.51]
				(p=0.207)
High risk groups for burning	78 (18.4%)	34 (13.8%)	44 (24.7%)	2.35 [1.38,
				3.98]
				(p=0.002)
The sun as a source of Vitamin D	98 (23.1%)	41 (16.6%)	57 (32.0%)	2.70 [1.65,
				4.42]
				(p<0.001)
Other ^c	1 (0.2%)	0 (0.0%)	1 (0.6%)	n/a
Does your school give out any advice regarding s	unscreen? ^b (n	= 468. missing	= 1)	
Sunscreen is recommended in the spring and	296 (63.2%)	174 (61.1%)	122 (66.7%)	1.21 [0.80,
summer term			(******	1.81]
				(p=0.366)
Sunscreen is encouraged during summer term	127 (27.1%)	81 (28.4%)	46 (25.1%)	0.93 [0.60,
only			, , , , , , , , , , , , , , , , , , ,	1.46]
				(p=0.766)
Sunscreen is recommended when the UV index	47 (10.0%)	27 (9.5%)	20 (10.9%)	0.98 [0.52,
is above 3				1.86]
				(p=0.952)
Parents are encouraged to send children in with	287 (61.3%)	172 (60.4%)	115 (62.8%)	1.03 [0.69,
sunscreen				1.53]
				(p=0.902)
Sunscreen is recommended for school	291 (62.2%)	180 (63.2%)	111 (60.7%)	0.85 [0.57,
trips/sports days especially				1.27]
			- (()	(p=0.427)
Other ^c	18 (3.8%)	11 (3.9%)	7 (3.8%)	n/a
What happens at your school regarding the appl	r		-	4.00 [0.07
Parents are encouraged to apply sunscreen to	449 (95.7%)	273 (95.5%)	176 (96.2%)	1.00 [0.37,
students before school				2.67]
	10 (2.00()	0 (2 40/)	0 (4 00/)	(p=1.000)
Parents are invited back at lunch to reapply	18 (3.8%)	9 (3.1%)	9 (4.9%)	1.80 [0.66,
sunscreen				4.90]
Toospars can only apply support on with	115 (24 50/)		42 (22 00/)	(p=0.250)
Teachers can only apply sunscreen with parental consent	115 (24.5%)	73 (25.5%)	42 (23.0%)	0.89 [0.57, 1.41]
				1.41) (p=0.634)
Teachers help students apply sunscreen,	87 (18.6%)	54 (18.9%)	33 (18.0%)	(p=0.834) 1.00 [0.60,
specific consent is not sought	07 (10.0%)	J4 (10.3%)	JJ (10.070)	1.64]
				(p=0.985)
Teachers are not allowed to help with	71 (15.1%)	44 (15.4%)	27 (14.8%)	0.92 [0.53,
sunscreen at all	, 1 (13.1/0)		-, (17.0/0)	1.59]
				(p=0.767)
		1		NP 0.707

	02 (40 02()	52 (42 20)	44 (22 49()	4 45 [0 74		
Specific time is given for application of	93 (19.8%)	52 (18.2%)	41 (22.4%)	1.15 [0.71,		
sunscreen before breaks, or as needed				1.88]		
				(p=0.563)		
We do not have any stated guidelines or rules	36 (7.7%)	30 (10.5%)	6 (3.3%)	0.32 [0.13,		
around sunscreen application				0.79]		
				(p=0.013)		
Other ^c	22 (4.7%)	11 (3.8%)	11 (6.0%)	n/a		
Is sun protective hat wearing encouraged at you	ır school (e.g a	hat with a brin	n or legionnaire	e cap)?ª (n =		
469)						
1= Yes, encouraged during summer term only	98 (20.9%)	59 (20.6%)	39 (21.3%)	1.45 [0.95,		
2= Yes, encouraged in spring and summer	304 (64.8%)	193 (67.5%)	111 (60.7%)	2.23]		
months				(p=0.089)		
3= Yes, hats are a part of the school uniform	39 (8.3%)	14 (4.9%)	25 (13.7%)			
Yes, encouraged only when UV index above 3 ^c	14 (3.0%)	9 (3.1%)	5 (2.7%)	n/a		
No, it is not actively encouraged ^c	4 (0.9%)	3 (1.0%)	1 (0.5%)	n/a		
Other ^c	10 (2.1%)	8 (2.8%)	2 (1.1%)	n/a		
What happens if a student does not bring their own hat when hat wearing is encouraged? ^b (n = 455)						
(Branching from above question, if "Yes,")						
They are encouraged to play in the shade	281 (61.8%)	176 (64.0%)	105 (58.3%)	0.77 [0.51,		
				1.15]		
				(p=0.205)		
They are encouraged to play indoors	43 (9.5%)	25 (9.1%)	18 (10.0%)	1.12 [0.58,		
				2.18]		
				(p=0.733)		
They can borrow hat from school 'spare hats'	175 (38.5%)	94 (34.2%)	81 (45.0%)	1.59 [1.07,		
				2.37]		
				(p=0.023)		
No restriction or consequence	121 (26.6%)	76 (27.6%)	45 (25.0%)	0.90 [0.58,		
·			. ,	1.41]		
	Y			(p=0.656)		
Other ^c	12 (2.6%)	7 (2.5%)	5 (2.8%)	n/a		
Ordinal legistic regression – the outputs are also						

1

^a Ordinal logistic regression – the outputs are alongside the responses that were included in the model. The

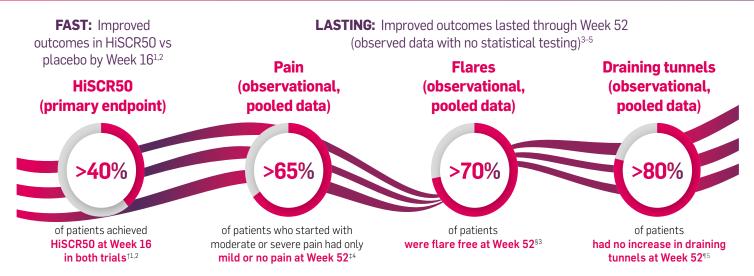
reference is the first category and ordered as in table.

2 3 ^b Multiple response question – n and percentages may not add up to the total or 100%

4 ^c Category excluded from regression analysis



Cosentyx can help to provide fast relief and lasting control for your eligible patients with HS³



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 trials³

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.¹²

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.¹² Please see above for the licensed dermatology indications.

¹HiSCR50: ≥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=181), respectively.¹²

¹The 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

⁸Flare, 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

¹Observed 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.



<u>Cosentyx* (secukinumab) Northern Ireland Prescribing</u> 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 nonradiographic 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 enthesitisrelated arthritis and juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. Presentations: Cosentyx 150 mg solution for injection in pre-filled pen; Cosentyx 300 mg solution for injection in pre-filled pen. Dosage & Administration: Administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consider discontinuation if no response after 16 weeks of treatment. Each 150 mg dose is given as one injection of 150 mg. Each 300 mg dose is given as two injections of 150 mg or one injection of 300 mg. If possible avoid areas of the skin showing psoriasis. Plaque Psoriasis: Adult recommended dose is 300 mg monthly. Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher. Adolescents and children from the age of 6 years: if weight \geq 50 kg, recommended dose is 150 mg (may be increased to 300 mg as some patients may derive additional benefit from the higher dose). If weight < 50 kg, recommended dose is 75 mg. However, 150mg solution for injection in pre-filled pen is not indicated for administration of this dose and no suitable alternative formulation is available. Psoriatic Arthritis: For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNFq 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

<u>Cosentyx® (secukinumab) Great Britain Prescribing</u> <u>Information.</u> Please refer to the Summary of Product Characteristics

(SmPC) before prescribing.

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< 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: Bare cases of anaphylactic reactions have been observed. If an anaphylactic or serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. Vaccinations: Do not give live vaccines concurrently with Cosentyx; inactivated or non-live vaccinations may be given. Paediatric patients should receive all age appropriate immunisations before treatment with Cosentyx. Latex-Sensitive Individuals: The removable needle cap of the 150mg pre-filled pen contains a derivative of natural rubber latex. Concomitant immunosuppressive therapy: Combination with immunosuppressants, including biologics, or phototherapy has not been evaluated in psoriasis studies. Cosentyx was given concomitantly with methotrexate, sulfasalazine and/or corticosteroids in arthritis studies. Caution when considering concomitant use of other immunosuppressants. Interactions: Live vaccines should not be given concurrently with secukinumab. No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in adult psoriasis study. No interaction between Cosentyx and methotrexate and/or corticosteroids seen in arthritis studies. Fertility, pregnancy and lactation: Women of childbearing potential: Use an effective method of contraception during and for at least 20 weeks after treatment. Pregnancy: Preferably avoid use of Cosentyx in pregnancy. Breast feeding: It is not known if secukinumab is excreted in human breast milk. A clinical decision should be made on continuation of breast feeding

dose is 75 mg. Hidradenitis suppurativa: Recommended dose is 300 mg monthly. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks. Contraindications: Hypersensitivity to the active substance or excipients. Clinically important, active infection. Warnings & Precautions: Infections: Potential to increase risk of infections: serious infections have been observed. Caution in patients with chronic infection or history of recurrent infection. Advise patients to seek medical advice if signs/symptoms of infection occur. Monitor patients with serious infection closely and do not administer Cosentyx until the infection resolves. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab in the psoriasis clinical studies. Should not be given to patients with active tuberculosis (TB). Consider anti-tuberculosis therapy before starting Cosentyx in patients with latent TB. Inflammatory bowel disease (including Crohn's disease and ulcerative colitis): New cases or exacerbations of inflammatory bowel disease have been reported with secukinumab. Secukinumab, is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, secukinumab should be discontinued and appropriate medical management should be initiated. Hypersensitivity reactions: Bare cases of anaphylactic reactions have been observed. If an anaphylactic or serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. Vaccinations: Do not give live vaccines concurrently with Cosentyx; inactivated or non-live vaccinations may be given. Paediatric patients should receive all age appropriate immunisations before treatment with Cosentyx. Latex-Sensitive Individuals: The removable needle cap of the 75mg and 150 mg pre-filled syringe and 150mg pre-filled pen contains a derivative of natural rubber latex. Concomitant immunosuppressive therapy: Combination with immunosuppressants. including biologics, or phototherapy has not been evaluated in psoriasis studies. Cosentyx was given concomitantly with methotrexate, sulfasalazine and/or corticosteroids in arthritis studies. Caution when considering concomitant use of other immunosuppressants. Interactions: Live vaccines should not be given concurrently with secukinumab. No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in adult psoriasis study. No interaction between Cosentyx and methotrexate and/or corticosteroids seen in arthritis studies. Fertility, pregnancy and lactation: Women of childbearing potential: Use an effective method of contraception during and for at least 20 weeks after treatment. Pregnancy: Preferably avoid use of Cosentyx in pregnancy. Breast feeding: It is not known if secukinumab is excreted in human breast milk. A clinical decision should be made on continuation of breast feeding during Cosentyx treatment (and up to 20 weeks after discontinuation) based on benefit of breast feeding to the child and benefit of Cosentyx therapy to the woman. Fertility: Effect on

during Cosentyx treatment (and up to 20 weeks after discontinuation) based on benefit of breast feeding to the child and benefit of Cosentyx therapy to the woman. Fertility: Effect on human fertility not evaluated. Adverse Reactions: Very Common (≥1/10): Upper respiratory tract infection. Common (≥1/100 to <1/10): Oral herpes, headache, rhinorrhoea, diarrhoea, nausea, fatigue. Uncommon ($\geq 1/1,000$ to <1/100): Oral candidiasis, lower respiratory tract infections, neutropenia, inflammatory bowel disease. Rare ($\geq 1/10.000$ to <1/1.000): anaphylactic reactions. exfoliative dermatitis (psoriasis patients), hypersensitivity vasculitis. Not known: Mucosal and cutaneous candidiasis (including oesophageal candidiasis). Infections: Most infections were non-serious and mild to moderate upper respiratory tract infections, e.g. nasopharyngitis, and did not necessitate treatment discontinuation. There was an increase in mucosal and cutaneous (including oesophageal) candidiasis, but cases were mild or moderate in severity, non-serious, responsive to standard treatment and did not necessitate treatment discontinuation. Serious infections occurred in a small proportion of patients (0.015 serious infections reported per patient year of follow up). Neutropenia: Neutropenia was more frequent with secukinumab than placebo, but most cases were mild, transient and reversible. Rare cases of neutropenia CTCAE Grade 4 were reported. Hypersensitivity reactions: Urticaria and rare cases of anaphylactic reactions were seen. Immunogenicity: Less than 1% of patients treated with Cosentyx developed antibodies to secukinumab up to 52 weeks of treatment. Other Adverse Effects: The list of adverse events is not exhaustive, please consult the SmPC for a detailed listing of all adverse events before prescribing. Legal Category: POM. MA Number & List Price: EU/1/14/980/005 150 mg pre-filled pen x2 £1,218.78; EU/1/14/980/010 - 300 mg pre-filled pen 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 <u>www.mhra.gov.uk/yellowcard</u>. 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

human fertility not evaluated. <u>Adverse Reactions</u>: Very Common (\geq 1/10): Upper respiratory tract infection. Common ($\geq 1/100$ 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 nonserious and mild to moderate upper respiratory tract infections, e.g. nasopharyngitis, and did not necessitate treatment discontinuation. There was an increase in mucosal and cutaneous (including oesophageal) candidiasis, but cases were mild or moderate in severity, non-serious, responsive to standard treatment and did not necessitate treatment discontinuation. Serious infections occurred in a small proportion of patients (0.015 serious infections reported per patient year of follow up). Neutropenia: Neutropenia was more frequent with secukinumab than placebo, but most cases were mild, transient and reversible. Rare cases of neutropenia CTCAE Grade 4 were reported. Hypersensitivity reactions: Urticaria and rare cases of anaphylactic reactions were seen. Immunogenicity: Less than 1% of patients treated with Cosentyx developed antibodies to secukinumab up to 52 weeks of treatment. Other Adverse Effects: The list of adverse events is not exhaustive, please consult the SmPC for a detailed listing of all adverse events before prescribing. Legal Category: POM. MA Number & List Price: PLGB 00101/1205 - 75 mg pre-filled syringe x 1 - £304.70; PLGB 00101/1029 - 150 mg pre-filled pen x2 £1,218.78; PLGB 00101/1030 - 150 mg pre-filled syringe x2 £1.218.78: PLGB 00101/1198 - 300 mg pre-filled pen x 1 £1218.78. Pl Last Revised: June 2023. Full prescribing information, (SmPC) is available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255

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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