

# Use of sunscreens for approved indications

This bulletin focuses on prescribing of sunscreens for Advisory Committee on Borderline Substances (ACBS) approved indications. Borderline substances are mainly foodstuffs but also include some toiletries, such as sun blocks for use by people with conditions such as photodermatoses. Sunscreens protect skin against ultraviolet (UV) radiation, which is divided into ultraviolet A (UVA) and ultraviolet B (UVB). This bulletin provides the available evidence for use in the approved indications described below.

### Recommendations

- Ensure that prescribing of sunscreens is in line with ACBS approved indications.<sup>1</sup>
- If ACBS prescribing criteria are not met, then review and stop prescribing the sunscreen.
- For optimum photoprotection:<sup>2,3</sup>
  - » Use sunscreens from spring to autumn in people with photodermatoses.
  - » Apply sunscreens thickly and frequently (approximately two hourly).
- Prescribe sunscreen preparations with highest sun protection factor (SPF) to provide maximum protection, (protects against UVB) and 4 or 5 star rating (protects against UVA). Preparations with SPF less than 30 should not normally be prescribed.
- Review all patients on sunscreens:
  - » Check indications for using a sunscreen.
  - » Advise any patients who don't meet the ACBS approved indication to purchase an appropriate sunscreen over-the-counter (OTC).
  - » Remind patients that sunscreens are not a substitute for covering the skin and avoiding sunlight.
  - » Regularly review effectiveness of sunscreens.
  - » Regularly review patients who meet the ACBS criteria to ensure they are using the sunscreen correctly (applying them thickly and liberally. approximately every two hours).
  - » Endorse all prescriptions with "ACBS".

### Background

Sunscreens marked as 'ACBS' in the British National Formulary (BNF) are regarded as drugs when prescribed for skin protection against UV radiation in abnormal cutaneous photosensitivity. This includes genetic disorders, photodermatoses, including vitiligo and those resulting from radiotherapy; chronic or recurrent herpes simplex labialis.<sup>1</sup> Prescribing for other indications is not permitted on FP10.

Photodermatoses are a group of skin conditions associated with an abnormal reaction to UV radiation. Whereas UVB is the predominant factor in causing sunburn, UVA is largely responsible for photodermatoses. These are classed as either photosensitive or photoaggravated photodermatoses.

#### **Photosensitive dermatoses**

Photosensitive dermatoses are caused by light and include polymorphic light eruption (PLE), actinic prurigo, chronic actinic dermatitis, solar urticaria, hydroa vacciniforme. Most are immunologically-mediated except those related to chemicals (drugs, porphyria) and DNA repair (xeroderma pigmentosum). The BNF states that certain drugs, such as demeclocycline, phenothiazines, or amiodarone, can cause photosensitivity.<sup>1</sup>

#### **Photoaggravated dermatoses**

Photoaggravated dermatoses are pre-existing skin conditions that can be made worse with light in exposed areas of skin, e.g. cutaneous lupus erythematosus, dermatomyositis, herpes simplex, Darier's disease, pellagra, some cases of rosacea and vitiligo.<sup>3,4</sup>

### **Sunscreens**

Topical sunscreens are broadly divided into organic (chemical) and inorganic (physical) filters.<sup>5</sup>

#### **Inorganic sunscreens**

Inorganic sunscreens (also known as 'physical', 'natural', 'reflective', 'zinc') contain titanium dioxide or zinc oxide, which reflect UV radiation away from the skin and scatter UVB, UVA and visible radiation by forming an opaque barrier of inert metal particles. They may also absorb UV radiation depending on their particle size. They are often cosmetically unacceptable due to their white appearance.

#### **Organic sunscreens**

Organic sunscreens (also known as 'absorbers' or 'chemical' sunscreens) act by absorbing UV radiation, shielding against UVB, UVA or both. Different agents are specific for given wavelengths so are often combined to obtain broad-spectrum protection. Adverse events from organic sunscreen use occur more often in patients with photodermatoses, and can include allergic and irritant contact dermatitis, phototoxic and photoallergic reactions, contact urticaria and in rare cases anaphylactic reactions.<sup>5</sup>

### Protection against UVA and UVB radiation

The amount of protection offered against UVB radiation is indicated by the Sun Protection Factor (SPF) of the preparation. This number shows the multiples of protection provided against burning, compared to unprotected skin. For example, SPF30 enables a person to stay thirty times longer in the sun without burning than would be the case if no sunscreen were applied. SPFs are rated on a scale of 2-50+ based on the level of protection they offer, with ratings between 2 to 14 at the least protected and ratings of 50+ offering the strongest forms of UVB protection.

No standard method exists to measure the UVA protection of sunscreens.<sup>5</sup> However, the star system is generally accepted. Stars are categorized on a scale from 0 to 5, with 5 providing the highest and 0 the lowest protection. They indicate the percentage of UVA radiation absorbed by the sunscreen in comparison to UVB. A sunscreen with an SPF of 30 and a UVA rating of 4 or 5 stars is generally considered a good standard of sun protection.<sup>6</sup>

New EU recommendations advise that as well as the SPF number, the SPFs are categorised as providing low to very high protection, to make the SPF guide easier to understand. The below table illustrates this:<sup>6</sup>

New label	SPF	
Low protection	6 to 14 (i.e. SPF 6 and 10)	
Medium protection	15 to 29 (i.e. SPF 15, 20 and 25)	
High protection	30 to 50 (i.e. SPF 30 and 50)	
Very high protection	50 + (i.e. SPF 50+)	

According to the EU recommendation, the UVA protection for each sunscreen should be at least a third of the labelled SPF. A product that achieves this requirement is labelled with a UVA logo, the letters "UVA" printed in a circle.

Sunscreens are more effective against UVB than UVA radiation. Patients should use a high UVB-SPF with a 4 or 5 star rating to protect against UVA.<sup>3</sup>

## **Clinical evidence**

The National Institute for Health and Care Excellence (NICE) Guideline NG34 "Sunlight exposure: communicating the benefits and risks to the general population" does not give specific guidance on the use of sunscreens in abnormal skin photosensitivity from photodermatoses, genetic disorders, vitiligo, radiotherapy or rosacea.<sup>7</sup> The efficacy of sunscreens has been well documented in polymorphic light eruption (PLE), solar urticaria, and lupus erythematosus.<sup>8</sup>

Key to the management of photodermatoses is photoprotection, which includes seeking shade; wearing photoprotective clothing, wide brimmed hats, and sunglasses; and applying sunscreens. Sunscreens with a SPF over 30 that incorporate photostabilized UVA filters are usually the appropriate choice for adequate photoprotection.<sup>8</sup>

The European Dermatology Guidelines for photoprotection acknowledge the efficacy of broadspectrum, high protection sunscreens in the prevention of PLE.<sup>5</sup> However, they also report on the lack of compliance among patients suffering from photodermatoses and that this may account for the variable effect of sunscreens. In one study, the median application thickness was found to be only 0.5mg/cm<sup>2</sup> which reduced a declared SPF 50+ into an effective SPF of 2-3. The patients in this study reported only slight protection from previous use of sunscreens but after the study, and its consequent education of this patient group, much better protection was reported.

This is important since the use of a broad-spectrum sunscreen SPF 50+ in a correct amount has been shown to be highly effective in protecting very UV-sensitive patients suffering from idiopathic solar urticaria when tested in a standardised setting.<sup>9</sup>

This stresses the need for thorough instructions in sunscreen application, amount used and effect from correct use. The ears, temples, posterior and lateral neck tend to be completely overlooked. The prescriber must ensure patients are counselled in the appropriate application of sunscreens.<sup>10</sup>

### Costs

#### Table 1: ACBS approved sunscreen cost per pack<sup>2</sup>

Product	Cost per original pack <sup>2</sup>		
Anthelios® XL Melt-in cream (UVA ,UVB protection; UVB- SPF 50+)	50ml = £3.80		
Sunsense® Ultra Lotion (UVA ,UVB protection; UVB-SPF 50)	50ml roll-on = £5.01	125mL bottle = £8.14	500mL pump = £18.17
Uvistat® Cream (UVA ,UVB protection; UVB-SPF 30)	125ml = £7.45		
Uvistat® Cream (UVA ,UVB protection; UVB-SPF 50)	125ml = £8.45		
Uvistat® Lipscreen (UVA ,UVB protection; UVB-SPF 50)	5g = £2.99		

## Savings available

In England and Wales, nearly £1.4 million is spent on sunscreens per year (ePACT, January to December 2015). This excludes products for photodamage.

Prescribing 50% fewer sunscreens would save around £700,000 in England and Wales over 12 months. This equates to savings of £1137 per 100,000 patients.

## **Options to review therapy**

Ensure all patients prescribed sunscreens on FP10 prescriptions meet the ACBS criteria. The only ACBS approved indication is for skin protection against UV radiation in abnormal cutaneous photosensitivity. This includes genetic disorders, photodermatoses, vitiligo from radiotherapy and chronic or recurrent herpes simplex labialis.<sup>2</sup>

Discontinue any prescribing for:

- Sunscreens other than the five products listed in table 1 as these are the only sunscreen products which meet ACBS criteria.
- Patients who do not meet ACBS criteria. Advise these patients to purchase an appropriate sunscreen over-the-counter (OTC) instead. Further information on sun safety for patients is available from the British Association for Dermatologists and NHS Choices.<sup>6</sup>

### **Summary**

- Prescribing of sunscreens is governed by the Advisory Committee on Borderline Substances. FP10s
  ordering sunscreens should be endorsed "ACBS". All other prescribing should be discontinued and
  OTC purchase advised for those who wish to continue using them. Substantial savings can be achieved
  by reviewing prescribing.
- The amount of protection offered against UVB radiation is indicated by the SPF of the preparation.
- No standard method exists to measure the UVA protection of sunscreens. However, the star system is generally accepted. Star values of 5 reflect highest protection, and 0 the lowest.

## References

- 1. Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press. October 2015 <u>http://www.evidence.nhs.uk/formulary/bnf/current/a2-borderline-substances</u> Accessed 24th October 2015
- Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press. October 2015 <u>http://www.evidence.nhs.uk/formulary/bnf/current/13-skin/138-sunscreens-and-camouflagers/1381-sunscreen-preparations</u> Accessed 24th October 2015
- 3. Primary Care Dermatology Society UK (PCDS). Photodermatoses: An overview. <u>www.pcds.org.uk/</u> <u>clinical-guidance/photodermatoses</u> Accessed 25th October 2015
- 4. Patient UK. Photodermatoses. <u>http://patient.info/doctor/photodermatoses</u> Accessed 25th October 2015
- 5. European Dermatology Guideline for the photodermatoses. 3. Photoprotection. <u>www.euroderm.</u> <u>org/edf/index.php/edf-guidelines/category/3-guidelines-on-photodermatoses</u> Accessed 11th August 2015.
- 6. British Association of Dermatologists Sunscreen Fact Sheet <u>http://www.bad.org.uk/for-the-public/</u> <u>skin-cancer/sunscreen-fact-sheet</u> Accessed 26th October 2015
- 7. National Institute of Health and Care Excellence. NICE Guidelines NG34. February 2016, Sunlight exposure: Risks and benefits. http://www.nice.org.uk/guidance/ng34 Accessed 22nd February 2016
- 8. Medeiros VL, Lim HW. Sunscreens in the management of photodermatoses. Skin Therapy Lett 2010; 15 (6): 103.
- 9. Faurschou A, Wulf HC. Synergistic effect of broad-spectrum sunscreens and antihistamines in the control of idiopathic solar urticarial. Archives of Dermatology 2008; 144 (9): 765-9.
- 10. Azurdia RM, Pagliaro JA, Diffey BL et al. Sunscreen application by photosensitive patients is inadequate for protection. Br J Dermatol 1999; 140: 255-8.

## Additional PrescQIPP resources





Patient information leaflet

Available here: https://www.prescqipp.info/our-resources/bulletins/bulletin-138-sunscreens/

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Non-subscriber publication July 2016.

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