

Sunscreen, broad-spectrum

REJECTED

The Expert Committee, after evaluation, declines to list the medicine proposed in the application.
The Model List of Essential Medicines reports reasons that Committee Members have identified for denying listing.

Section: 13. Dermatological medicines > 13.7. Dermatological medicines > Sunscreens

| | | EMLc | ATC codes: Pending |
|--------------------------|--|------|--------------------|
| Indication | Albinism or other specified genetically-determined hypomelanotic disorders ICD11 code: EC23.2 | | |
| Medicine type | Chemical agent | | |
| List type | Core (EML) (EMLc) | | |
| Formulations | Topical cream, lotion, gel, ointment, spray with sun protection factor ≥ 50 . | | |
| EML status history | Application rejected in 2023 (TRS 1049) | | |
| Sex | All | | |
| Age | Also recommended for children | | |
| Therapeutic alternatives | The recommendation is for this specific medicine | | |
| Patent information | Patents have expired in most jurisdictions Read more about patents . | | |
| Wikipedia | Sunscreen, broad-spectrum | | |

Expert Committee recommendation

The Expert Committee acknowledged that people with albinism and xeroderma pigmentosum were a subgroup of the general population that has a significantly higher risk of skin cancer due to the harmful effects of UV radiation on their unprotected skin and for whom use of broad-spectrum sunscreen is an important preventive intervention. The Committee similarly acknowledged the public health relevance and effectiveness of sunscreen in preventing skin cancer in both the general population and persons with albinism. The Committee agreed that globally promoting the use of sunscreens, as well as other sun-protection and sun-avoidance strategies and behaviours, was a crucial preventive measure to reduce the incidence and prevalence of skin cancers, including melanoma. The Committee noted that the burden of disease of such cancers is increasing and that their treatment is associated with significant costs for both individuals and health systems, especially in low- and middle-income settings. The Committee recognized the importance of effective preventive interventions in addressing this growing public health burden. The Committee recalled that broad-spectrum sun protection products had previously been included on the EML for the general population but were recommended for removal in 2005. In making this recommendation, the 2005 Expert Committee acknowledged the high public health relevance of topical sun protection agents for the prevention of skin cancer but noted that "sunscreens are normally not provided by public facilities and that provision through such sources was not needed." However, the Committee noted that many different sunscreen products exist on the global market, containing a wide variety of organic agents (which absorb UV radiation) and/or inorganic agents (which reflect or scatter UV radiation). Sunscreen products also vary widely in their sun protection factor rating. Furthermore, the Committee noted that national standards and regulations of sunscreen products also vary considerably between countries – in some settings, they are regulated as therapeutics, while in others they are regulated as non-therapeutic so-called cosmetic products. The Committee considered that before being able to recommend sunscreen products for inclusion on the Model Lists, it would be necessary to define relevant standards and specifications for therapeutic (as distinct from cosmetic) sunscreen products protecting against both UVA and UVB rays (broad spectrum). This would include details of specific active ingredients and their concentration and the range of sun protection factor rating. This information needs to be supported by

evidence and implications for labelling standards to provide clear and reliable guidance for countries for selection and procurement of the most appropriate sunscreen products. The Expert Committee therefore did not recommend the inclusion of sunscreen on the EML and EMLc for the prevention of skin cancer in people with albinism or xeroderma pigmentosum at this time. The Committee recommended that WHO undertake the necessary work to inform a resubmission for the consideration of sunscreen products by the 2025 Expert Committee. One member of the Expert Committee held a different opinion in relation to this recommendation and was in favour of the inclusion of sunscreen on the Model Lists for the prevention of skin cancer in people with albinism and xeroderma pigmentosum. It was this person's opinion that the use of sunscreen in this extremely vulnerable subgroup of people represents an essential preventive public health intervention for skin cancer in low- and middle-income countries, and that EML listing would help to ensure availability of quality-assured sunscreen products.

Background

Currently, there are no sun protection agents on the EML or EMLc. P-aminobenzoic acid (PABA) and benzophenones with SPF 15 were first added to the EML in 1989. In 1991, zinc oxide was added as an agent to prevent skin cancer induced by ultraviolet (UV) light in people whose occupations expose them to sun. However, in 1995 p-aminobenzoic acid was removed. In 1997, the benzophenones and zinc oxide were replaced by a broad-spectrum topical sun protection. In 2005, all sun protection agents were removed from the EML. At the time, the Committee noted the high public health relevance but justified removal on the basis that sunscreens were not normally provided by public facilities (1).

Public health relevance

Albinism is a rare, non-contagious, genetic congenital condition characterized by decreased or absent pigmentation (i.e. lack of melanin pigment) in the hair, skin and/or eyes. Albinism occurs worldwide regardless of ethnicity or sex. The incidence of albinism in western societies has been documented to range from 1:14 000 to 1:17 000. In African countries, it is said to range between 1:1500 and 1:15 000 (2). A high incidence of albinism ranging from 1:28 to 1:6500 has also been reported in indigenous communities in the Americas (3). Due to the reduced or absent melanin in the skin, patients with albinism are highly susceptible to the harmful effects of UV radiation and are at increased risk of acute and chronic actinic damage to their skin, in particular solar elastosis, actinic keratosis and skin cancers (4–6). Exposure of people with albinism to the sun without sun protection is a cause of premature death from skin cancer, in addition to causing high morbidity and reduced quality of life due to premature skin photo-ageing, multiple skin lesions and scarring following surgical excision of malignant skin lesions. For example, people with albinism in Africa (where there is higher UV radiation) are reportedly 1000 times more likely to develop squamous cell carcinoma than the general population (7). Other studies show that persons with albinism predominantly develop skin cancers by the time they are 20 and do not commonly live beyond the age of 30 years (8,9). The use of sunscreen is important for all persons with albinism regardless of geographic location, including regions with relatively low incidence of UV radiation (10). The application also provided information on the public health relevance in the context of human rights, government/legislation and nongovernmental organizations. Human rights Access to sunscreen by persons with albinism is a right in terms of Article 12 of the International Covenant on Economic, Social and Cultural Rights (11), which enshrines the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, as well as Article 25 of the Convention of the Rights of Persons with Disabilities (12), particularly Article 25(b) which requires states to, “provide those health services needed by persons with disabilities specifically because of their disabilities”. The UN Committee on the Rights of Persons with Disabilities and the UN Independent Expert on albinism have recognized the visual impairment and lack of melanin in persons with albinism as disabilities (13,14). Providing access to sunscreen for persons with albinism also aligns with the UN Sustainable Development Goal to ensure healthy lives and promote well-being for all at all ages (SDG 3). Government and legislation Government programmes and existing laws support the public health imperative relative to sunscreen as an essential medicine for persons with albinism. Several countries (e.g. Brazil and Uganda) have provided subsidies for people with albinism to obtain sunscreen. The Executive Council of the African Union adopted a Plan of Action on Ending Attacks and Discrimination against People with Albinism in July 2019. Section 4.3(a) of the implementation matrix for the plan of action calls on state members of the African Union to, “ensure access to health support, services and health goods such as visual aids and sunscreen for all persons with albinism particularly in rural areas and with emphasis on skin cancer prevention and treatment as well as specialist services for low vision and dermatological care” (15). Nongovernmental organizations Some nongovernmental organizations have recognized the public health imperative for persons with albinism by creating programmes to meet their need for sun protection. Three nongovernmental organizations serving people with albinism in various countries in Africa, and whose programmes include local production of sunscreen, are Beyond Suncare,

Benefits

The topical application of broad-spectrum sunscreens is recommended as a safe adjunct measure in protecting human skin from UV radiation when other protection measures (e.g. clothing or sun avoidance) cannot be used or are insufficient. In the context of persons with albinism, sunscreen use is considered part of healthy sun protection practices (16). Research has shown the benefits of using sunscreen in reducing the incidence of skin cancer (17). A randomized trial of 1621 adults in Australia evaluated daily sunscreen application (SPF 15+) versus no daily sunscreen for the prevention of squamous cell and basal cell carcinomas (18). After 4.5 years of follow-up, no significant differences were reported in the incidence of first new skin cancers between the daily sunscreen and no daily sunscreen groups: basal cell carcinoma 2588 versus 2509 per 100 000; rate ratio (RR) 1.03, 95% confidence interval (CI) 0.73 to 1.46 and squamous cell carcinoma 876 versus 996 per 100 000; RR 0.88, 95% CI 0.50 to 1.56). In terms of the number of tumours, no effect was observed on the incidence of basal cell carcinoma by sunscreen use. However, the incidence of squamous cell carcinoma was significantly lower in the daily sunscreen group than the no daily sunscreen group (1115 versus 1832 per 100 000; RR 0.61, 95% CI 0.46 to 0.81). After a further 8 years of follow-up, a non-significant decrease in basal-cell carcinoma tumour rates was found in the daily sunscreen group compared with the no sunscreen group. For squamous-cell carcinoma tumour rates, a significant decrease was observed in the daily sunscreen group compared with the no sunscreen group (RR 0.62, 95% CI 0.38 to 0.99) (19). A 2022 study using data from the United States National Health and Nutritional Examination Survey (2015–2016) evaluated the association of sunscreen use, sun avoidance and wearing of protective clothing with skin cancer prevalence (20). Sunscreen use was the only one of the three interventions that showed a statistically significant reduction in skin cancer prevalence (odds ratio (OR) 3.75, 95% CI 1.78 to 8.89). A retrospective study compared the effects of sun exposure on the occurrence of skin cancers in 22 participants with albinism and 30 without albinism (21). The average ages of participants with and without albinism with skin cancers were 34.6 years and 65.1 years, respectively. Of the participants with skin cancers, about 43% those with albinism and 80% of those without albinism reported prolonged sun exposure. Of note, among participants with albinism who had used sunscreen since childhood, 2/19 (10.5%) developed skin cancer, while of participants with albinism who did not use sunscreen, 20/27 (74.1%) developed skin cancer. A 2021 expert panel review investigated the effect of solar wavelength according to skin phototype and dermatoses, and proposed the need for tailoring recommendations for sunscreen type accordingly, as well as taking into consideration geographical latitude and altitude (22). For example, protection against UVB radiation is especially important for light skin as there is a high risk of sunburn, DNA damage and skin cancers. Darker skin may be naturally better protected against UVB but is more prone to hyperpigmentation induced by visible light and UVA radiation. For the prevention of skin cancers, the expert panel recommended daily use of sunscreen with high SPF (50+) and good UVA protection factor, and a SPF to UVA protection factor ratio between 1 and 3.

Harms

Concerns about the toxicity of UV filters and reduced vitamin D synthesis related to the use of sunscreen have been raised. The management of sunscreens must therefore balance their essential protective effect against the potential toxicity of the UV filters for humans and the environment. Photoallergic reactions are the most common adverse effect of topical sunscreens. This effect is particularly associated with the benzophenone class of organic UV filters. Contact dermatitis and photoallergy have also been reported with ethylhexyl methoxycinnamate and octocrylene (23). Allergenic effects are rare with mineral UV filters (e.g. titanium dioxide), but concerns have been raised about systemic absorption of micronized particles (23). A review of titanium dioxide in nanoparticle form found no evidence of carcinogenicity, mutagenicity or toxicity following dermal exposure. However, there are restrictions in Europe on the use of nanoparticle titanium dioxide formulations that can lead to lung exposure through inhalation (e.g. spray and powder products) (24). A quasi-experimental study conducted during winter in Brazil evaluated vitamin D synthesis with suberythemal sun exposure in 95 adults (25). Participants were randomized to one of three groups: use of SPF 30 sunscreen on the face, neck and chest (n = 64), no sunscreen (n = 10) or no sun exposure (n = 21). No difference was found between the sunscreen and no sunscreen groups for change in vitamin D level from baseline to 24 hours after sun exposure (5.4 ng/mg, 95% CI 4.4 to 6.5 ng/mg versus 4.1 ng/mg, 95% CI 2.5 to 6.0 ng/mg, P < 0.01). A literature review of sunscreen photoprotection and vitamin D status identified nine controlled studies on the effect of daily/recreational sunscreen use on vitamin D synthesis (26). Of the nine studies identified, seven showed no change in serum vitamin D with sunscreen use. Two studies found a reduction in vitamin D levels with sunscreen use. However, these studies did not consider important factors that may have influenced the outcome, such as personal

UV exposure, sunscreen application thickness and exposed body surface area. The authors of the review concluded that broad-spectrum sunscreen use was unlikely to compromise vitamin D status in healthy populations. Sunscreens may cause environmental harm (17). In this regard, some regulatory agencies have updated the indications, doses, labelling and testing of over-the-counter sunscreen agents (27).

Cost / cost effectiveness

Skin cancer is a significant cost and population burden for many countries and expenditure will grow as incidence increases. Public investment in skin cancer prevention and early detection programmes suggest health and economic benefits (29). While many persons with albinism are aware of the need to protect themselves from the harmful effects of UV radiation, studies have shown that they are prevented from doing so due to the cost of sunscreen, as well as cost of travel and travel distance to enable them to obtain sunscreen (30). Studies have concluded that systematic sunscreen use at a population level will prevent substantial numbers of new skin lesions and reduce the costs of treatment and loss of life (31–33). This is especially relevant for persons with albinism because of their higher risk of developing skin lesions. An Australian study evaluated daily versus discretionary sunscreen use, considering use of health-care resources, costs and health outcomes of basal-cell carcinoma and squamous cell carcinoma prevention (33). From a societal perspective, over 5 years, the net costs for daily versus discretionary sunscreen use were US\$ 329 149 and US\$ 222 700, respectively. The cost for the daily sunscreen group was offset in part by reduced costs for medical treatment as a result of skin cancers and actinic keratoses avoided. From the Australian government perspective (as funder of medical care for treatment of skin cancers), daily sunscreen use was cost-saving compared with discretionary sunscreen use.

WHO guidelines

WHO guidelines for the use of sunscreen are not currently available. WHO recommends the use of broad-spectrum sunscreen on skin areas that cannot be covered by clothes, as one of a series of recommended measures to protect against excessive UV exposure (28).

Availability

Sunscreens are available as personal care products or over-the-counter medicines in most middle- and high-income countries. Definitions and labelling standards are set by regulatory agencies.

Other considerations

The technical team in cancer in the WHO Department of Noncommunicable Diseases reviewed and provided comments on the application. The technical team advised that based on the available evidence, it supported the inclusion of topical sunscreen in multiple dosage forms on the EML and EMLc to reduce the risk of skin cancer in the target population.

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