Sunscreen, broad-spectrum

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

EMLc

Codes ATC: En attente

Indication	Albinism or other specified genetically-determined hypomelanotic disorders Code ICD11: EC23.2
Type de médicament	Chemical agent
Type de liste	Liste de base
Formulations	Topical: Therapeutic broad-spectrum sunscreens should contain proven active ingredients in appropriate amounts to absorb or filter UVA and UVB radiation, and have a high sun protection factor (SPF).
Historique des statuts LME	Demande refusée en 2023 (TRS 1049) Ajouté en 2025 (TRS 1064)
Sexe	Tous
Âge	Aussi recommandé pour les enfants
Équivalence thérapeutique	La recommandation concerne ce médicament spécifique
Renseignements sur le brevet	Patents have expired in most jurisdictions Lire la suite sur les brevets.
Wikipédia	Sunscreen, broad-spectrum

Recommandation du comité d'experts

The Expert Committee recognized the public health relevance of broad-spectrum sunscreen for the prevention of skin cancer in people with albinism, a population at significantly elevated risk of UV-induced skin damage and skin cancers. The Committee acknowledged that sunscreen is often the only feasible barrier to UV exposure for exposed skin, particularly where clothing or shade is insufficient. The Committee noted that no treatments are currently listed on the EML or EMLc for the prevention of UV-induced skin damage or skin cancer in people with albinism. While sunscreens were previously included on the EML, they were removed in 2005 due to challenges that provision was not a public sector remit, despite their demonstrated efficacy. The Committee acknowledged that the previous decision to remove sunscreens from the Model List may have negatively impacted people with albinism, as provision for this high-risk group should be recognized as a public sector responsibility. The Committee accepted the effectiveness and safety of broad-spectrum sunscreens in reducing the risk of skin cancer in all populations. The Committee considered that the protective role of sunscreen in preventing skin cancer was especially relevant in high-risk groups, such as people with albinism. The Committee also highlighted that sunscreen use alone should not be the only sun protection strategy used and stressed the importance of other measures (where possible) such as sun avoidance, shade seeking and sun-protective clothing. The Committee considered that the application addressed the concerns of the 2023 Expert Committee in presenting information on international standards for SPF determination, as well as recommended active sunscreen ingredients, their concentration and their spectrum of activity. However, the Committee noted that there remains a lack of evidence to support a specific formulation or formulations. The Committee noted that the absence of a recommended specific formulation presents a challenge, as the Model List is expected to guide procurement by identifying products available on the market. This gap limits its ability to fulfill one of its core functions in

supporting standardized selection and supply. The Committee noted that regular sunscreen use has been found to be a cost-effective intervention, with treatment costs offset by reduced costs for medical treatment of skin cancers, particularly in high-risk populations. However, the Committee acknowledged that affordability and access to broad-spectrum sunscreen products are still major barriers in many resource-constrained settings. The Committee considered that inclusion of sunscreen on the Model Lists could help to promote improved affordability and access by facilitating pooled procurement, attracting donor support and including sunscreen in universal health coverage schemes. Based on these considerations, the Expert Committee recommended the inclusion of therapeutic broad-spectrum topical sunscreen on the EML and EMLc for the prevention of skin cancer in people with albinism. The Committee recognized the higher susceptibility to the harmful effects of UV radiation, including (but not limited to) non-melanoma skin cancer, among people with albinism and the therapeutic need for effective and safe sun protection products in this population. Therapeutic broad-spectrum sunscreens should contain proven active ingredients in appropriate amounts to absorb or filter UVA and UVB radiation and have a high SPF. The Committee was not able to recommend specific formulations for listing at this time. The Committee considered that listing sunscreens, even without a preferred formulation, was important to stimulate greater investment in research to compare and identify among the various formulations available those with a better profile. The Committee invited the submission of proposals outlining optimal formulation specifications for future consideration by the Expert Committee.

Contexte

Sunscreen products are not currently included on the Model Lists. Previous listings of p aminobenzoic acid, benzophenones, zinc oxide and broad-spectrum topical sunscreen (containing 3% octyl methoxycinnamate, 2% titanium dioxide and 2% butyl methoxydibenzoylmethane) were removed from the EML in 2005. The Expert Committee noted that while sunscreens were effective in preventing squamous cell skin cancer in susceptible individuals, they were not normally provided by public facilities (1). An application for the re-introduction of topical sunscreen products on the Model Lists for the prevention of skin cancer in people with albinism was considered by the Expert Committee in 2023 (2). The Committee acknowledged that people with albinism had a significantly higher risk of skin cancer due to the harmful effects of ultraviolet (UV) radiation and were a population for whom the use of broad-spectrum sunscreen was an important preventive intervention. The Committee also acknowledged the public health relevance and effectiveness of sunscreen in preventing skin cancer in both the general population and in people with albinism. The Committee noted that many different sunscreen products were available on global markets, containing a wide variety of organic agents (which absorb UV radiation) and/or inorganic agents (which reflect of scatter UV radiation). Sunscreen products also vary widely in their sun protection factor rating and are subject to different regulatory standards (e.g. regulated as therapeutics or as cosmetic products) in different jurisdictions. 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 radiation. This would include evidence-based details of specific active ingredients and their concentration, and the range of sun protection factor rating. The Expert Committee therefore did not recommend listing at that time but requested WHO undertake the necessary work to inform a resubmission for consideration in 2025.

Pertinence pour la santé publique

Albinism is a genetic condition characterized by decreased or absent pigmentation (melanin) in the hair, skin and/or eyes. Melanin is crucial for protecting the skin from sun damage. Individuals with albinism are highly vulnerable to UV radiation, which significantly increases their risk of skin cancer and other UV-induced skin disorders. The lack of melanin in people with albinism leads to a higher susceptibility to acute and chronic actinic damage, including solar elastosis, actinic keratosis and skin cancers (3–5). Albinism occurs worldwide, with varying prevalence rates. In European countries, the prevalence ranges from 1:14 000 to 1:17 000, while in African countries, prevalence ranges from 1:1500 to 1:15 000 (6, 7). Studies have shown that people with albinism in some African countries are 1000 times more likely to develop squamous cell carcinoma than the general population (8, 9). Additionally, individuals with albinism predominantly develop skin cancers by the time they are

20 years old and often do not live beyond the age of 30 years (8, 10, 11). Further studies have shown that, without sunscreen, children with albinism can develop chronic skin damage from as young as 12 months (12). The development of skin cancer in persons with albinism is correlated to their occupation, with occupations that chronically expose skin to sunlight associated with higher occurrence of skin cancers (13).

Bénéfices

No new evidence for benefits was presented in the current application compared with the previous application. The following summary is reproduced from the technical report of the 2023 Expert Committee meeting (2). 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 (14). Research has shown the benefits of using sunscreen in reducing the incidence of skin cancer (15). 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 (16). 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 rates of basal-cell carcinoma tumour was found in the daily sunscreen group compared with the no sunscreen group. For rates of squamous-cell carcinoma tumour, 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) (17). 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 (18). Sunscreen use was the only intervention that showed a statistically significant reduction in skin cancer prevalence (odds ratio 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 (19). 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. 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 (20). 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 an SPF to UVA protection factor ratio between 1 and 3.

Torts

No new evidence for harms was presented in the current application compared with the previous application. The following summary is reproduced from the technical report of the 2023 Expert Committee meeting (2). 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. Allergenic effects are rare with mineral UV filters (e.g. titanium dioxide), but concerns have been

raised about systemic absorption of micronized particles (21). 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) (22). A quasi-experimental study conducted during winter in Brazil evaluated vitamin D synthesis with suberythemal sun exposure in 95 adults (23). 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 (24). Seven of the studies showed no change in serum vitamin D with sunscreen use. Two studies found a reduction in vitamin D levels with sunscreen use. However, the studies did not consider important factors that may have influenced the outcome, such as personal UV exposure, thickness of sunscreen application 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 (15). In this regard, some regulatory agencies have updated the indications, doses, labelling and testing of over-the-counter sunscreen agents (25).

Preuves supplémentaires

The application presented a summary of active sunscreen ingredients with approved concentration ranges as listed by selected regulatory agencies (United States Food and Drug Administration, Health Canada, Australian Therapeutic Goods Administration, Medsafe New Zealand, and EU Cosmetic Regulation No 1223/2009), refer to Table 10, TRS 1064. The International Organization for Standardization (ISO) provides standards for sun protection test methods and the determination of sun protection factor and UVA-protection factor of sunscreens. The application stated that sunscreen is a complex product in which the final formulation is crucial. However, evidence is lacking to support one particular formulation over any others. Therapeutic broad-spectrum sunscreens should be formulated and tested according to the relevant ISO standards, have an SPF of 50+ and filter both UVA and UVB radiation. The UVA to UVB ratio is recommended to be 1:3. The International League of Dermatological Societies advocates for the use of broad-spectrum sunscreen with a minimum SPF of 30 in populations at risk of skin cancers, including individuals with albinism. The guidelines stress the importance of reapplication after swimming or sweating to maintain effective protection (26).

Rapport coût/efficacité

No new costs or cost–effectiveness data were presented in the current application compared with the previous application. The following summary is reproduced from the technical report of the 2023 Expert Committee meeting (2). 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 (28). While many people 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 the cost of travel and travel distance to enable them to obtain sunscreen (29). 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 (30–32). An Australian study evaluated daily versus discretionary sunscreen use and considered the use of health-care resources, costs and health outcomes from the prevention of basal-cell carcinoma and squamous cell carcinoma (32). From a societal perspective, over 5 years, the net costs for daily versus discretionary sunscreen use were 329 149 United States dollars (US$) and US$ 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.

Directives de l'OMS

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 (27). Various national and international dermatology societies recommend regular application of a water-resistant, broad-spectrum sunscreen providing UVA and UVB protection and with an SPF of at least 30 (sometimes 50), in addition to other sun protection measures.

Disponibilité

Sunscreens are widely available as personal care products or over-the-counter medicines in most middle- and high-income countries. Availability and affordability in lower-income countries are more limited. The application highlighted that availability and affordability will need to be supported by government programmes in lower-income settings. Definitions and labelling standards are set by national regulatory agencies.

Autres considérations

From the human rights perspective, the United Nations Human Rights Committee has stated that “the obligation of States parties to respect and ensure the right to life extends to reasonably foreseeable threats and life-threatening situations that can result in loss of life” (33). Access to sunscreen by people with albinism is a right under Article 12 of the International Covenant on Economic, Social and Cultural Rights (34), 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 (35), particularly Article 25(b) which requires states to “provide those health services needed by persons with disabilities specifically because of their disabilities”.

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