

A.43	Sunscreen – prevention of skin cancer in people with albinism, xeroderma pigmentosum – EML and EMLc
Draft recommendation	<input type="checkbox"/> Recommended <input checked="" type="checkbox"/> Not recommended Justification: <p>The application requests the addition of a broad spectrum sunscreen (of factor 50+) on the core Lists of Essential Medicines (EML) and Essential Medicines for children (EMLc) for persons with albinism. While it is important for sunscreen protection for people with albinism, sunscreens are registered differently across the globe, either through medicine regulatory authorities, or by food and cosmetic agencies. The USA, Australia, and Japan consider sunscreen as medicinal products subject to the strict requirement of manufacture under GMP conditions like other drugs. Sunscreens are considered cosmetic products in the EU; however, the quality requirements are equally high. Regulation in emerging markets and developing countries is variable. ¹Thus, assuring quality, and affordability would be difficult. In addition, sunscreens are normally not provided by public facilities.</p>
Does the proposed medicine address a relevant public health need?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: <p>Different agencies register sunscreen as a cosmetic or as a medicine. Therefore this is a difficult question to address. This application is submitted specifically for persons with albinism, whose condition results in greatly increased risk of the harmful effects of ultraviolet radiation on unprotected skin, and could use sunscreen as a protective agent.</p>
<p>Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication?</p> <p>(this may be evidence included in the application, and/or additional evidence identified during the review process)</p>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: Most common types of sunscreens presently in use are the topical preparations, designated as physical and chemical sunscreens. Various systemic agents in the form of antioxidants, vitamins and minerals, designated as systemic sunscreens, have emerged as new photo-protective measure. The main goals of sunscreens are to protect against UVB radiation and long-wavelength UVA radiation, scavenge ROS, activate cellular repair systems, including DNA repair. ^{2 3} Regular use of sunscreens prevents the development of solar keratoses and, by implication, possibly reduces the risk of skin cancer in the long-term. ⁴⁵

¹ Kaimal S, Abraham A. Sunscreens. Indian Journal of Dermatology, Venereology and Leprology. 2011 Mar 1;77:238

² Sano T, Kume T, Fujimura T, Kawada H, Moriwaki S, Takema Y: The formation of wrinkles caused by transition of keratin intermediate filaments after repetitive UVB exposure. Arch Dermatol Res. 2005;296:359-65.

³ Krutmann J: Ultraviolet A radiation-induced biological effects in human skin: relevance for photoaging and photodermatitis. J Dermatol Sci. 2000;23:22-6

⁴ Thompson SC, Jolley D, Marks R. Reduction of solar keratoses by regular sunscreen use. N Engl J Med. 1993 Oct 14;329(16):1147-51. doi: 10.1056/NEJM199310143291602. PMID: 8377777.

⁵ Pinto D, Trink A, Giuliani G, Rinaldi F. Protective effects of sunscreen (50+) and octatrienoic acid 0.1% in actinic keratosis and UV damages. J Investig Med. 2022 Jan;70(1):92-98. doi: 10.1136/jim-2021-001972. Epub 2021 Sep 16. PMID: 34531252; PMCID: PMC8717479.

<p>Does adequate evidence exist for the safety/harms associated with the proposed medicine?</p> <p>(this may be evidence included in the application, and/or additional evidence identified during the review process)</p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: Inorganic sunscreens though considered to be relatively safe can pose potential health risks due to their formulation as nanoparticles which may potentially be absorbed systemically. The inhibitory effect of sunscreen on vitamin D synthesis have also been described.⁶ Other studies show that sunscreen use has no effect on the synthesis of Vitamin D.⁷ More comprehensive studies are required to establish the accurate association between sunscreen use and vitamin D status.</p>
<p>Are there any adverse effects of concern, or that may require special monitoring?</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: Sunscreens are not registered as medicines in most countries. Rather they are registered as cosmetics. Different evidence requirements apply for registration.</p>
<p>Are there any special requirements for the safe, effective and appropriate use of the medicines?</p> <p>(e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: These are topical agents generally, that are self-administered and therefore requiring no special requirements for administration.</p>
<p>Are there any issues regarding cost, cost-effectiveness, affordability and/or access for the medicine in different settings?</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: Available over the counter globally. Some studies have indicated that these can be costly for people in low and lower middle income countries.⁸⁹</p>

⁶ Libon F, Courtois J, Le Goff C, Lukas P, Fabregat-Cabello N, Seidel L, Cavalier E, Nikkels AF. Sunscreens block cutaneous vitamin D production with only a minimal effect on circulating 25-hydroxyvitamin D. Archives of osteoporosis. 2017 Dec;12:1-7

⁷ Hansen L, Tjønneland A, Køster B, Brot C, Andersen R, Lundqvist M, Christensen J, Olsen A. Sun exposure guidelines and serum vitamin D status in Denmark: The statusD study. Nutrients. 2016 May 5;8(5):266

⁸ Emily A. Weig, Rechelle Tull, Jina Chung, Zoe O. Brown-Joel, Rumbidzai Majee & Nkanyenzi N. Ferguson (2020) Assessing factors affecting sunscreen use and barriers to compliance: a cross-sectional survey-based study, Journal of Dermatological Treatment, 31:4, 403-405, DOI: 10.1080/09546634.2019.1587147

⁹ Wright CY, Norval M. Solar Ultraviolet Radiation, Skin Cancer and Photoprotective Strategies in South Africa. Photochemistry and Photobiology. 2023 Mar;99(2):509-18.

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<p>Are there any issues regarding the registration of the medicine by national regulatory authorities?</p> <p>(e.g. accelerated approval, lack of regulatory approval, off-label indication)</p>	<p><input checked="" type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments: Sunscreens are not registered as medicines in most countries. Rather they are registered as cosmetics. Different quality assurance processes apply as to registration requirements. Physicochemical and microbiological characterization of the final product is required to establish its compliance with required quality parameters. The specific tests include the visual analysis, stability testing, pH determination, SPF evaluation, determination of water resistance and its microbiological evaluation.</p>
<p>Is the proposed medicine recommended for use in a current WHO guideline?</p> <p>(refer to: https://www.who.int/publications/who-guidelines)</p>	<p><input type="checkbox"/> Yes</p> <p><input checked="" type="checkbox"/> No</p> <p><input type="checkbox"/> Not applicable</p> <p>Comments:</p> <p>“During its meeting in 2003, the Committee recommended that sun protection agents be reviewed for possible fast-track deletion at the meeting in 2005. A review was received from the ISDB. Despite this removal, the Committee noted that the use of topical sun protection agents (sunscreen products) containing substances that protect the skin against ultraviolet radiation (UVA and UVB) prevents squamous cell skin cancer in susceptible people. The Committee also noted the high public health relevance of this item for the prevention of skin cancer but appeared to justify its removal on the basis that sunscreens are normally not provided by public facilities and that provision through such sources was not needed.”</p>