

| A.6 | Calcipotriol (calcipotriene) – psoriasis |
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| Does the application adequately address the issue of the public health need for the medicine? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: |
| Briefly summarize the role of the proposed medicine(s) relative to other therapeutic agents currently included in the Model List, or available in the market. | <p>“While Calcipotriol is effective in individual patients with psoriasis in plaque type lesions. It is less effective than potent topical corticosteroids for psoriasis of the scalp”</p> <p>It can be applied to flexural skin to decrease the risk of developing striae distensae when these areas are being treated with steroids(1).</p> |
| Have all important studies and all relevant evidence been included in the application? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable If no, please provide brief comments on any relevant studies or evidence that have not been included: |
| Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable <p>Briefly summarize the reported benefits (e.g. hard clinical versus surrogate outcomes) and comment, where possible on the actual magnitude and clinical relevance of benefit associated with use of the medicine(s).</p> <p>It seems to be effective for the treatment of plaque type psoriasis and as efficacious as potent topical corticosteroids and other alternative topical agents.</p> <p>Is there evidence of efficacy in diverse settings (e.g. low-resource settings) and/or populations (e.g. children, the elderly, pregnant patients)?</p> <p>Studies on children cited in the application concern a limited number of children (58 and 77 children).</p> |
| Does the application provide adequate evidence of the safety and adverse effects associated with the medicine? | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: |
| Are there any adverse effects of concern, or that may require special monitoring? | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: |

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| Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.) | Favourable |
| Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.) | High |
| Are there any special requirements for the safe, effective and appropriate use of the medicine(s)? (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc) | <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: in such cases, its use should be accompanied by monitoring of serum calcium levels |
| Are you aware of any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication) | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: |
| Is the proposed medicine recommended for use in a current WHO Guideline approved by the Guidelines Review Committee? (refer to: https://www.who.int/publications/who-guidelines) | <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: |
| Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings. | The cost-utility contribution is not proven. Further studies on the impact of using calcipotriol, on the cost of side effects and quality of life should be carried out. |
| Any additional comments | |
| Based on your assessment of the application, and any additional evidence / relevant information identified during the review process, briefly summarize your proposed recommendation to the Expert Committee, including the supporting rationale for your conclusions, and any doubts/concerns in relation to the listing proposal. | <p>the efficacy of calcipotriol compared to a placebo is well established, however compared to topical corticosteroids the usefulness of the product is not obvious except in cases of intolerance to corticosteroids.</p> <p>The study of the potential contribution of the medicine and its impact on the cost of the management of the disease should be more thorough.</p> |
| References (if required) | <p>(1) Emmanuel Mahé, Maud Amy De La Bretèque & Céline Phan (2021) Perspectives on the pharmacological management of psoriasis in pediatric and adolescent patients, Expert Review of Clinical Pharmacology, DOI: 10.1080/17512433.2021.1911641</p> <p>(2) https://www.jaad.org/article/S0190-9622(19)32655-6%20/fulltext (more recent than the 5th cited article)</p> |