

A.28	Silver Diamine fluoride – dental caries
<p>Does the application adequately address the issue of the public health need for the medicine?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable</p> <p>Comments:</p>
<p>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>	<p>SDF application can arrest the progression of existing and prevent the incidence of dental caries by approximately 80%. The procedure itself consists of placing a drop of the solution in a dental dappen dish and then applying a small amount on the dried tooth surface with a disposable micro brush or applicator. The procedure is pain-free and arrested carious lesions do not cause further pain and infection. SDF treatment is therefore a minimally invasive alternative for treatment for dental caries and is also indicated for people unable to tolerate conventional treatment due to their specific condition</p>
<p>Have all important studies and all relevant evidence been included in the application?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable</p> <p>If no, please provide brief comments on any relevant studies or evidence that have not been included:</p>
<p>Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable</p> <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). The reviews provided demonstrated that topical application of SDF was effective in arresting dentinal caries in preschool children , and the overall percentage of active carious lesions arrested was as high as 81%. Compared with other management options or placebos, the application of SDF is more effective. With 2-year follow-up, the application of SDF reduced the development of new dentinal carious lesions significantly, compared with placebo, no treatment, or fluoride vanish. Regarding older people, SDF has been found effective in arresting and preventing root caries.. Annual SDF application arrested root caries at 30-month follow-up by 90%.</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)? Yes</p>

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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: No severe harm and adverse health outcomes due to the application of SDF have been reported. The available evidence indicates that it is safe to use SDF as a topical agent to prevent or arrest dental caries in both child and adult population.
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:
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	The overall risk to benefit ratio is favourable
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	The overall quality of the evidence is 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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments:
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 checked="" type="checkbox"/> Yes <input 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.	Topical application of SDF is considered a cost-effective method to prevent and manage dental caries. Since application is possible by community health workers or other trained personnel (non-dentists) the additional implementation costs of programmes using SDF are much lower than other dentist-led other forms of fluoride applications.

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Any additional comments	None
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.	This application form relates to the inclusion of Silver Diamine fluoride (AgF(NH ₃) ₂ , also known as Silver Diamine Fluoride (SDF), as part of the new subgroup 30.1 on both the EML and the EMLc. A modification to the existing entry for “sodium fluoride” in group 27 is requested. Based on the information provided, there is a convincing rationale for accepting this application. I recommend that the expert committee accepts this application
References (if required)	