

A.28	Silver Diamine Fluoride - for arresting and preventing 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>"The rationale for the modification and addition of a new category for dental medicines and medical devices is grounded in the significant burden of oral diseases, particularly untreated dental caries. Oral diseases are major public health problems in all countries worldwide."</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).</p> <p>"It is effective in preventing and arresting dentine caries in primary and permanent teeth with preventive fractions of 60% and 80% (respectively) across the lifespan for the crowns of primary and permanent teeth, as well as the root surfaces of permanent teeth."</p> <p>"Role of SDF in therapy includes the antibacterial effects of silver and the remineralizing effects of fluoride"</p> <p>However, according to the meta-analysis (14th reference) cited in the application: "the evidence on the preventive effect of SDF is based on only two small positive clinical trials with important limitations regarding study design and implementation"</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>Is there any evidence when used for children</p>

2021 Expert Committee on Selection and Use of Essential Medicines
Application review

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:
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	Favorable for treatment Uncertain for prevention
Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: Registration as drug could be not possible in some countries as the dossier should respond to a specific organization. We should find different modules for active substances, formulation development, preclinical and toxicological studies and clinical studies (efficacy-toxicity) studies which could not be evident for a medical device
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.	
Any additional comments	

2021 Expert Committee on Selection and Use of Essential Medicines
Application review

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.	Favourable for curative use and not for prevention
References (if required)	(1) Fraihat N, Madae'en S, Bencze Z, Herczeg A, Varga O. Clinical Effectiveness and Cost-Effectiveness of Oral-Health Promotion in Dental Caries Prevention among Children: Systematic Review and Meta-Analysis. Int J Environ Res Public Health. 2019;16(15):2668. Published 2019 Jul 25. doi:10.3390/ijerph16152668