

A.19	Inclusion of Hypromellose - Treatment of Dry Eye Disease– EML/EMLc
Draft recommendation	<input type="checkbox"/> Recommended <input checked="" type="checkbox"/> Not recommended Justification: Artificial tears are categorized differently as medical devices, over-the-counter (OTC) drugs or prescription drugs in the different markets.
Does the proposed medicine address a relevant public health need?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: Dry eye disease (DED) has a global prevalence ranging from approximately 5% to 50%, corresponding to 385 million to 3.85 billion people worldwide, and is present in all World Health Organization (WHO) region: the African region, the South-East Asian region, the Eastern Mediterranean region, the Western Pacific region, the European region, and the region of the Americas. However, artificial tears treat symptoms only. Not all patients with dry eye disease benefit from artificial tears.
Does adequate evidence exist for the efficacy/effectiveness of the medicine for the proposed indication? (this may be evidence included in the application, and/or additional evidence identified during the review process)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: Artificial tears present a proven treatment option for DED patients to improve symptoms (but not clinical signs). Artificial tears are often effective in treating certain symptoms [artificial tears such as Hypromellose are reported to effectively treat dry eyes and consistently improve ocular symptoms such as burning and irritation], although they do not include classical active pharmaceutical ingredients (APIs), and head-to head comparisons in clinical DED trials presents a major challenge that resulted in a high failure rate and several discontinued projects. ¹² The comparison of available DED drugs showed that the products are approved for different indications like “Increasing tear production” or “treatment of signs and symptoms of DED”.
Does adequate evidence exist for the safety/harms associated with the proposed medicine? (this may be evidence included in the application, and/or additional evidence identified during the review process)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable Comments: Over-the-counter (OTC) hypromellose is generally safe, with occasional transient burning and stinging of the eyes.

¹ Pucker A, Marrone M, Nichols JJ. Over the counter (OTC) artificial tear drops for dry eye syndrome (Protocol). The Cochrane Library. 2012, Issue 3.

² Nichols KK, Evans DG, Karpecki PM. A Comprehensive Review of the Clinical Trials Conducted for Dry Eye Disease and the Impact of the Vehicle Comparators in These Trials. Curr Eye Res. 2021; 46(5): 609-614.

24th WHO Expert Committee on Selection and Use of Essential Medicines
Expert review

<p>Are there any adverse effects of concern, or that may require special monitoring?</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable</p> <p>Comments: Stinging and burning sensation in the eyes is a mild adverse effect most commonly observed in patients who experience adverse effects using hypromellose and may compromise compliance with treatment.</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 <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable</p> <p>Comments: These are self administered topical applications.</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 <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable</p> <p>Comments: These are over-the-counter preparations that are available at low costs.</p>
<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 type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable</p> <p>Comments: Artificial tears are categorized differently as medical devices, over-the-counter (OTC) drugs or prescription drugs in the different markets.</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 <input checked="" type="checkbox"/> No <input type="checkbox"/> Not applicable</p> <p>Comments:</p>