## Melatonin 1mg/ml Oral Solution Sugar Free (Licensed)

## To PAEDIATRIC PATIENTS

This ready reckoner is to aid product selection when dispensing <u>melatonin 1mg/ml oral solution sugar free</u> for <u>paediatric</u> patients.

There are currently four products available on the market licensed for use in children:

- Three generic products (manufactured by Colonis, Consilient and Aspire)
- Branded Ceyesto<sup>®</sup> (manufactured by Alturix).

Additional generic products are available but are licensed for <u>adults</u> and therefore outside the scope of this document.

Note: pharmacists have a professional responsibility to ensure any medicine is suitable for the patient. The <u>NPPG Position Statement</u> advises, when choosing an oral liquid medicine for a child, the following must be considered:

- 1. Excipient content, including quantity and suitability (see table 1 below)
- 2. Cumulative daily excipient intake from all products being taken.
- 3. Potential adverse effects due to excipients.
- 4. The risk-benefit analysis of using an unlicensed product vs. a licensed product

5. The concentration of the product and the dose volume. Ideally the dosing volume should not be less than 0.2mL or more than 10mL, though it may be necessary to administer smaller volumes within neonatal critical care. Where smaller volumes are required, consideration should be given to how these can be safely administered to minimise the potential for error.

6. Any local agreement on use of standard concentrations, in both Primary and Secondary care.

If the pharmacist has concerns as to the appropriateness of a particular product, they should discuss these with the prescriber.

## The following table provides information on potential dispensing choices of the four melatonin 1mg/ml oral solution sugar free products currently licensed for use in children:

TABLE 1: Comparison Melatonin 1mg/ml Oral Solution Sugar Free Adapted from Regional Drug and Therapeutics           Centre (RDTC):			
Manufacturer	Excipient (s) with known effect in paediatrics	Pack size AND Shelf life after first opening	Dispensing Comments In consideration of excipients with known effect.
Aspire	<ul> <li>Methyl parahydroxybenzoate: 1 mg per 1 ml</li> </ul>	Pack size =150mls Shelf Life: 2 months	AN option for children of all ages if required (Note: Use in children under 6 years may be off-label see SPC)
Colonis	<ul> <li>Propylene glycol: 150.50 mg per 1 ml</li> <li>Sorbitol: 140 mg per 1 ml</li> </ul>	Pack size = 60mls, 150mls Shelf life: 2 months	ONLY an option for children > 5 years due to propylene glycol content. (Note: Use in children under 6 years is off-label see SPC)
Consilient Health	<ul> <li>Methyl parahydroxybenzoate: 1 mg per 1 ml</li> </ul>	Pack size = 150mls AND 100mls Shelf life: 6 months	AN option for children of all ages if required. (Note: Use in children under 6 years is off-label see SPC)
Alturix Ltd (Ceyesto <sup>®</sup> )	<ul> <li>Benzyl alcohol: 6 mg per 1 ml</li> <li>Propylene glycol: 52 mg per 1 ml.</li> <li>Each 1 ml of oral solution contains 1 mg of sodium</li> </ul>	Pack size = 100mls and 150mls Shelf life: 1 month	ONLY an option for children ≥ 6years due to benzyl alcohol and propylene glycol content. (Note: Use in children under 6 years may be off-label see SPC)

Refer to Specialist Pharmacy Services for further advice on excipient content in paediatric medicines.

This document is accurate only at point of issue 09/06/2025. It should be used in conjunction with the references documented. This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer.