

# Extemporaneous Compounding of Oral Liquid Morphine Preparations



National Department of Health

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Affordable Medicines Directorate  
Essential Drugs Program

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Adult Hospital Level Standard Treatment  
Guidelines and Essential Medicines List



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# New formulation: morphine oral solution



	1mg/ml	5mg/ml	10mg/ml
Morphine Hydrochloride/ Sulphate powder	0.1g	0.5g	1g
Nipastat 0.15 solution, make up to	100ml	100ml	100ml

*Nipastat® 0.15% procured as pre-made solution. Contains methylhydroxybenzoate (2.5g), propylhydroxybenzoate (1.25g), alcohol 99% (125mL), purified water to 2.5L.*

*NSN = 222001625*

See: [https://www.health.gov.za/wp-content/uploads/2024/10/AHL-STG-Erratum\\_Appendix-IV\\_Extemporaneous-Preparations-Morphine-Reformulation\\_03-October-2024.pdf](https://www.health.gov.za/wp-content/uploads/2024/10/AHL-STG-Erratum_Appendix-IV_Extemporaneous-Preparations-Morphine-Reformulation_03-October-2024.pdf)



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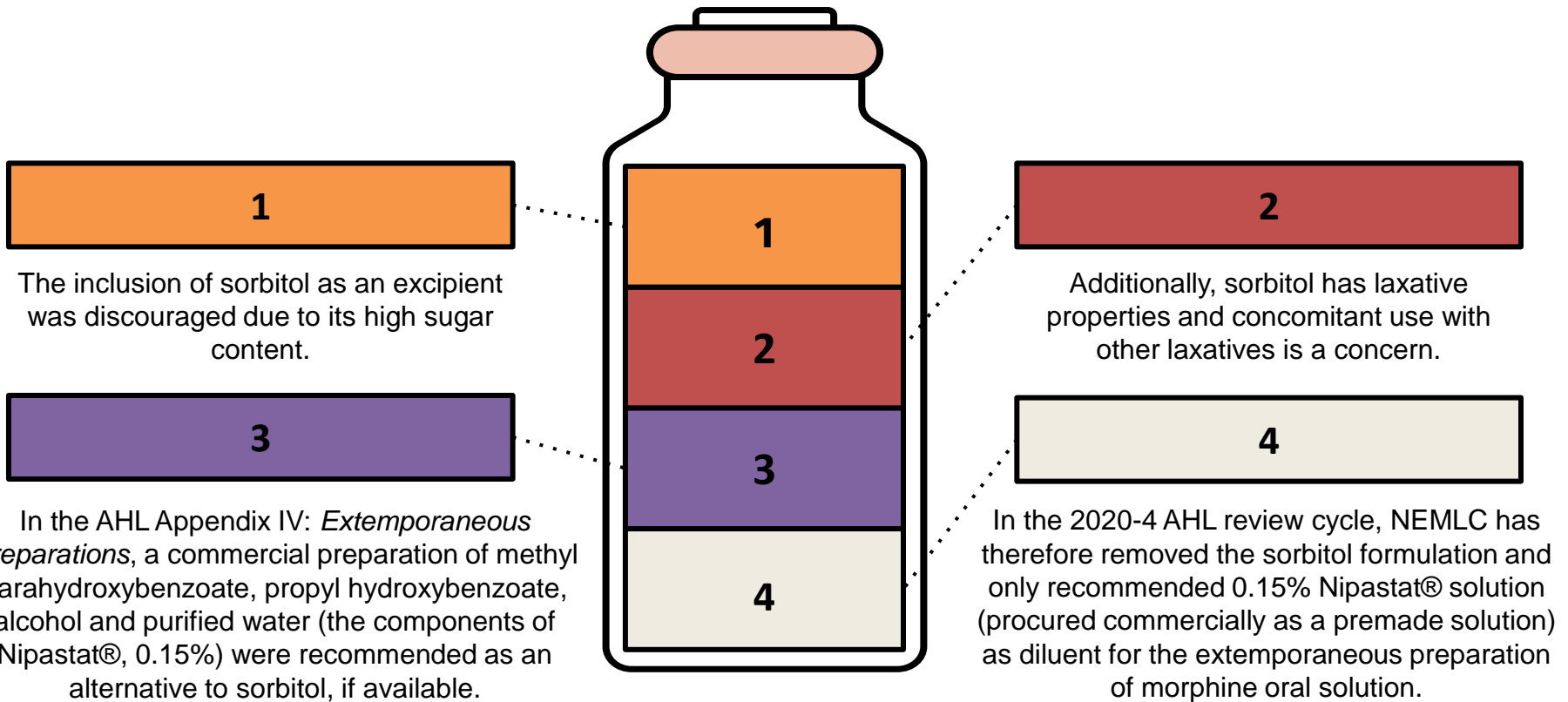
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# Formulation considerations



**NEMLC recommended the following updates for compounding morphine oral solution in adults and children above the age of 6 years old:**

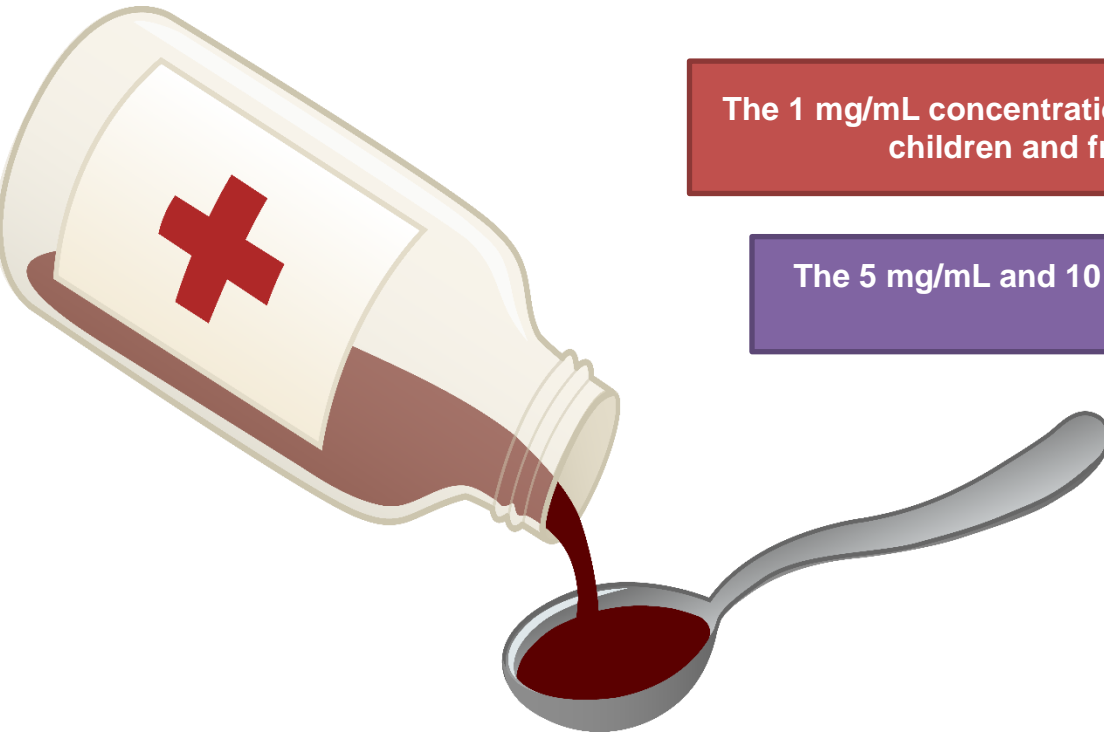


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# Standard concentrations



The 1 mg/mL concentration of morphine oral solution is recommended for children and frail care patients where lower doses are required.

The 5 mg/mL and 10 mg/mL concentrations of morphine oral solution are recommended for adult patients.

The 20 mg/mL concentration of morphine oral solution is only recommended in patients with complex pain (e.g. opioid tolerant patients). This concentration will only be needed in oncology centres and specialist care settings.

For clarity, concentrations represented as a percentage (%) have been removed and concentrations expressed as mg/mL have been retained.



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# Shelf life of compounded preparations



NEMLC noted that extemporaneous compounding is performed in accordance with section 14(4) of the Medicines and Related Substance Act (Act 101 of 1965) and the accompanying Regulations

General Regulation 3, as amended in December 2022, only allows the preparation of an extemporaneous solution to be used for no more than 30 consecutive days from the date of sale.

In the public sector, the date of sale would be the date of issue by the pharmacy. To avoid wastage, especially at smaller facilities, NEMLC has recommended the inclusion of formulae for smaller final volumes of 100mL and 500mL of morphine oral solution.



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# Additional considerations for neonates, infants and young children



1

While the use of Nipastat® could be considered in children under the age of 6 years old, the high percentage of alcohol in this formulation is of concern in this group of patients. There is a lack of robust data on extemporaneous formulations for neonates, infants and younger children with available excipients and formulations.



2

It is recommended that a diluted morphine intravenous formulation be used orally (in consultation with specialists in units and your pharmacy department); e.g. Add 1ml of 10mg/ml IV solution to 9ml normal saline (preservative free), to make 1mg/ml concentration (to be stored in fridge for no longer than 7 days).

3

Alternative morphine extemporaneous formulations excluding the use of alcohol, for example use of the following excipients: Benzoic acid, propylene glycol, sorbitol and purified water can be considered.



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# Note



**Appendix IV: Extemporaneous preparations is currently under review, therefore the updated morphine, oral solution formulation guide will be published as part of the final Adult Hospital Level STG and EML 2024 edition, in due course. Refer to Annexure A for the complete guidance on the preparation of morphine oral solution.**

**[https://www.health.gov.za/wp-content/uploads/2024/10/AHL-STG-Erratum-Appendix-IV-Extemporaneous-Preparations-Morphine-Reformulation\\_03-October-2024.pdf](https://www.health.gov.za/wp-content/uploads/2024/10/AHL-STG-Erratum-Appendix-IV-Extemporaneous-Preparations-Morphine-Reformulation_03-October-2024.pdf)**



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