



health

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## ERRATUM TO THE ADULT HOSPITAL LEVEL STANDARD TREATMENT GUIDELINES AND ESSENTIAL MEDICINE LIST, 2019, 5<sup>TH</sup> EDITION.

Please note the following corrections to the Adult Hospital Level Standard Treatment Guidelines (STGs) and Essential Medicine List (EML), 2019, 5<sup>th</sup> edition: APPENDIX IV (EXTEMPORANEOUS PREPARATIONS).

The formula for morphine oral solution has been corrected as indicated below:

APPENDIX IV	EXTEMPORANEOUS PREPARATIONS		
<b>MORPHINE, ORAL SOLUTION</b>			
<ul style="list-style-type: none"> <li>Morphine, oral solution:               <ul style="list-style-type: none"> <li>1 mg/mL (0.1%)</li> <li>5 mg/mL (0.5%)</li> <li>20 mg/mL (2%)</li> </ul> </li> </ul>			
<b>Declaration:</b>			
<i>Active ingredient:</i> Morphine hydrochloride/sulphate 1 mg/mL; 5 mg/mL; 20 mg/mL			
<i>Dosage form:</i> Oral solution			
<i>Excipients:</i> Benzoic acid, propylene glycol, sorbitol, purified water			
<b>Formula:</b>			
	<b>1 mg/mL</b>	<b>5 mg/mL</b>	<b>20 mg/mL</b>
Morphine hydrochloride/sulphate	50-g <u>5 g</u>	250-g <u>25 g</u>	1000-g <u>100 g</u>
Benzoic acid solution 5%*	100 mL	100 mL	100 mL
Sorbitol 70%	1500 mL	1500 mL	1500 mL
Sterile water, add to	5000 mL	5000 mL	5000 mL
<i>(Smaller volumes can be formulated - calculate proportions).</i>			
<b>Preparation:</b>			
Dissolve the morphine in approximately 2000 mL of the purified water. Dissolve the benzoic acid solution 5% in this solution. Add the 70% sorbitol solution and a sufficient quantity of purified water to a volume of 5000 ml and mix well.			
<b>Quality requirements</b>			
<i>Identity:</i> as stated under the section "Declaration", above.			
<i>Content of morphine hydrochloride:</i> 90–110% of the declared amount, calculated as the pure substance.			

pH:  $\leq 4$

*Appearance:* The solution is clear and almost free of visible particles.

**Storage:** Glass amber bottle, below 25 °C with an expiry date of 1 month.

*\*To make the benzoic acid 5% solution:* Dissolve the benzoic acid in the propylene glycol, adding the hot purified water to a volume of 1000 mL.

Benzoic acid	50 g
Propylene glycol	750 mL
Sterile water, heated to $\pm 60^{\circ}\text{C}$ , add to	1000 mL

**Storage:** Glass amber bottle, below 25 °C with an expiry date of 1 month.

**Note:** Commercial preparation of methyl parahydroxybenzoate, propyl hydroxybenzoate, alcohol and purified water could be considered as the diluent for morphine, oral solution, if available.

## **PAEDIATRIC HOSPITAL LEVEL STGS AND EML**

### **Older children, adolescents**

*Use formula as recommended above.*

### **Neonates, infants and young children**

There is a lack of robust data on extemporaneous formulations for neonates, infants and younger children with available excipients and formulations in South Africa. It is thus recommended that for this group of patients 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).

### **Note:**

Tilidine drops are no longer available and no longer recommended in the updated Paediatric Hospital Level (5<sup>th</sup> edition) STGs and EML. Please refer to the updated document for guidance in specific indications: <https://knowledgehub.health.gov.za/content/standard-treatment-guidelines-and-essential-medicines-list>. See table 1: Dosing for oral morphine (immediate release liquid), for general dosing for management of pain.

## **CIRCULAR DISSEMINATION**

Provinces and Healthcare Facilities are requested to distribute and communicate this information in consultation with the Pharmaceutical and Therapeutics Committees. Kindly share with all healthcare professionals and relevant stakeholders.

Comments may be submitted via e-mail: [SAEDP@health.gov.za](mailto:SAEDP@health.gov.za)

Kind regards



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**CHIEF DIRECTOR: SECTOR WIDE PROCUREMENT**

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