



health

Department:  
Health  
REPUBLIC OF SOUTH AFRICA



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**NOTICE: RECOMMENDED THERAPEUTIC ALTERNATIVE FOR RANITIDINE INJECTION**

The Paediatric Hospital Level Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) currently recommends the use of either ranitidine intravenously (IV), or a proton pump inhibitor (PPI) such as pantoprazole IV for gastric erosions associated with burns, where patients are unable to take an oral PPI. The contracted supplier of ranitidine injection, Pharma-Q (Pty) Ltd has indicated that due to a variation rejection letter received from the South African Health Products Regulatory Authority (SAHPRA), ranitidine injection will no longer be supplied to provinces.

The product was previously recalled from the market due to ranitidine products containing N-Nitroso-dimethylamine (NDMA) that has attracted wide attention as being highly hepatotoxic and a known carcinogen. Although there are backorders in the system and Pharma-Q (Pty) Ltd has stock on hand, they are not allowed to supply the stock as per SAHPRA's regulations. In the absence of ranitidine IV, pantoprazole IV can be utilised. The management guidelines for gastric erosions associated with paediatric burns is outlined below:

**Gastric erosions**  
Preventative medication treatment is not given. Effective early resuscitation and early feeding decrease the incidence of gastric erosion.  
If gastric erosion is suspected due to haematemesis or brownish gastric aspirates.  
Proton pump inhibitor, e.g.

- Omeprazole, oral, 0.4–0.8 mg/kg/dose 12 hourly. Specialist initiated.
  - Maximum dose: 20–40 mg/dose.
  - If 1 month–2 years: 2.5 mg 12 hourly.
  - If > 2–6 years: 5 mg 12 hourly.
  - If > 7–12 years: 10 mg 12 hourly.

If unable to take orally:

- Proton pump inhibitor, e.g.
  - Pantoprazole, IV, 0.5 mg/kg/dose 12 hourly.

**OR**

- Ranitidine, IV, 1 mg/kg 6 hourly.

Pantoprazole IV injection is available on tender HP06-2021SVP as indicated below:

NSN	Product Description	Supplier Name
181753528	Pantoprazole; 40mg; injection; 1 Injection	Ranbaxy Pharmaceuticals (Pty) Ltd

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.

Kind regards

MS K JAMALOODIEN  
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