Strategy and Sustainability Division
MINISTRY FOR HEALTH, THE ELDERLY AND COMMUNITY CARE

DH CIRCULAR No.259/2010

DH 4030/2010

11th November 2010

Attention all Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: PPIs: Esomeprazole I.V. powder for reconstitution, 40-mg vial and Omeprazole I.V. injection powder for reconstitution 40-mg vial

Currently GHPS has started procuring esomeprazole I.V. 40mg powder for injection/infusion as a Proton Pump Inhibitor.

The following table summarizes the essential details of the esomeprazole injection/infusion and the omeprazole injection, as per the respective Summary of Product Characteristics (SPCs).

	Esomeprazole I.V. 40mg powder for solution for injection/infusion	**Omeprazole I.V. 40mg powder for solution for injection**
Licensed indications	Gastric antisecretory treatment when the oral route is not possible, e.g.: - GORD in patients with oesophagitis and/or severe symptoms of reflux - healing of gastric ulcers associated with NSAID therapy - Prevention of: a. gastric and duodenal ulcers associated with NSAID therapy, in patients at risk. b. rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.	- Prophylaxis of acid aspiration. - In patients who are unable to take oral therapy for the short-term treatment (up to 5 days) of reflux oesophagitis, duodenal and benign gastric ulcers, including those complicating NSAID therapy e.g. perioperative use.
Administration	**Injection**: The reconstituted solution should be given as an intravenous injection over a period of at least 3 minutes. **Infusion**: The reconstituted solution should be given as an intravenous infusion over a period of 10 to 30 minutes. **80 mg bolus dose**: The reconstituted solution should be given as a **continuous** intravenous infusion over 30 minutes.	Losec® powder and solvent for solution for injection is for intravenous administration **only** and must **not** be given by any other route. Duration of intravenous administration should be over 5 minutes.

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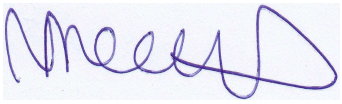
	8 mg/h dose: The reconstituted solution should be given as a **continuous** intravenous infusion over a period of 71.5 hours	
Instructions for use	Reconstituted solution should be made using 0.9% sodium chloride for intravenous use, where volume depends on method of administration.	Contents of the vial should be completely dissolved with the 10ml of solvent provided in the ampoule. No other solvents for I.V. injection should be used.
Use in impaired hepatic function	No dose adjustments for mild to moderate liver impairment in patients with GORD and bleeding ulcers.	Dose adjustment is required in impaired hepatic function, where a dose of 10mg-20mg may be sufficient.
Use in pregnancy and lactation	Caution should be exercised in pregnant women and should not be used during breast-feeding.	Can be used during pregnancy and is not likely to influence the child when therapeutic doses are used, though excreted in breast milk.
Shelf-life after reconstitution	Chemical and physical in-use stability has been demonstrated for 12 hours at 30^{o}C.	Once opened and reconstituted may be stored for a maximum of 4 hours at 25^{o}C.

Esomeprazole I.V. 40mg are available for use as per protocol number 152.

The Summary of Product Characteristics (SPC) for Esomeprazole clearly states that it should not be used in children since no data is available. Since there is some experience of use of omeprazole in children and the BNF® for children suggests its off-license use in this group, some stocks of Omeprazole I.V. 40mg are being kept at the pharmacy for this use as per protocol number 152.

Thank you

For your attention, please



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152

Proton Pump Inhibitors for Infusion

Prescriber Criteria: Consultant Gastroenterologist
Consultant Surgeon
Consultant Geriatrician
Consultant Anaesthetist

Hospital Use:

- Treatment of severe erosive oesophagitis, duodenal ulcer or gastric ulcers
- Upper GI bleeding
- Severely ill, hospitalized patients in whom oral therapy is inappropriate or in whom empiric therapy is envisaged for upper gastrointestinal bleeding as evidenced by coffee-ground vomiting, haematemesis, malaena.

The licensed dose is 40mg daily iv for a maximum of 5 days. Any other dosage regimen is considered as unlicensed and an off-license form is required.