



27 August 2020

Medicine Supply Alert Notice

Esomeprazole 40mg iv powder for solution (Grunenthal, Ranbaxy, Tillomed)

Priority: Level 2*
Valid until: Early 2021

Issue

1. Ranbaxy and Tillomed esomeprazole 40mg iv powder for solution is out of stock, limited supplies of Grunenthal product remain available but all stock is expected to be depleted w/c 24 August. Bowmed esomeprazole injection is available but unable to support an uplift in demand.
2. Ranbaxy expect a resupply in **early-mid September**, Tillomed in **mid-late September 2020** and Grunenthal in **early 2021**.
3. Specialist importers have indicated that unlicensed imports of esomeprazole injection can be sourced.
4. Alternative injectable proton pump inhibitors (PPIs) are available and can support an increase in demand should organisations choose to switch to an alternative product until the resolution of this shortage.

Advice and Actions

5. Board pharmacy procurement teams and clinical leads should work together to:
 - review local stock holding of the products and calculate if they anticipate a gap in supply based on forecast demand between now and the re-supply date of their contracted supplier;
 - consider if the gap in supply will be mitigated by using unlicensed imports or by a switch to an alternative PPI, further detail to aid a switch to an alternative PPI or import can be found in the supporting information section below;
 - prepare a local mitigation strategy identifying the risks associated with switching to an alternative product and working to mitigate these wherever possible; and
 - ensure clinical areas impacted are notified of this shortage with any patient safety risks clearly highlighted, before a switch is implemented.

Additional Information

6. The following specialist importers have confirmed they can source unlicensed esomeprazole injection, lead times vary:
 - Alium; and
 - Durbin.
7. Please note the information outlined above is correct on day of publication but may be subject to change and there may be other companies not listed above that can also source supplies. Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Board or local governance procedures. Please see the links below for further information:

- **Prescribing unlicensed medicines**, General Medical Council (GMC);
- **The supply of unlicensed medicinal products**, Medicines and Healthcare products Regulatory Agency (MHRA); and
- **Professional guidance for the procurement and supply of specials**, Royal Pharmaceutical Society (RPS).

8. UKMi have produced a table summarising the possible therapeutic alternatives, below, to aid Boards in switching if this is part of their local mitigation strategy.

Agent	Licensed indications	Adult dose	Paediatric dose	Method of administration	Comments
Esomeprazole 40mg powder for injection/infusion	Gastric antisecretory treatment when oral route not possible from age ≥ 1 year.	Age ≥ 12 years 20–40mg once daily.	Age 1–11 years: -Weight <20 kg: 10mg once daily -Weight ≥ 20 kg: 10mg or 20mg once daily	Injection: over ≥ 3 minutes Infusion -20 and 40 mg over 10 to 30 minutes 80 mg bolus dose intravenous infusion over 30 minutes Following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers: 80 mg bolus infusion over 30 minutes, followed by continuous intravenous infusion of 8 mg/h given over 72 hours	Contra-indications in patients with previous hypersensitivity reaction to drug or excipients in injection. Both omeprazole and esomeprazole contra-indicated in patients taking nelfinavir. For stat dose – potential for drug interactions not likely to be clinically significant.
Omeprazole 40 mg Powder for Solution for Infusion	Gastric antisecretory treatment when oral route not possible in adults.	40mg once daily Zollinger-Ellison Syndrome 60mg daily. Higher daily doses may be required.	Unlicensed* <u>Child 1 month–11 years</u> Initially 500 micrograms/kg once daily (max. per dose 20 mg), increased if necessary, to 2 mg/kg once daily (max. per dose 40 mg). <u>For Child 12–17 years</u> 40 mg once daily.	Intravenous infusion over 20–30 minutes.	However, when repeat doses are needed, potential for adverse drug interactions should be assessed. This is especially important for patients on omeprazole or esomeprazole and concomitant clopidogrel or antiretroviral medicines atazanavir or nelfinavir
Pantoprazole 40 mg powder for solution for injection	Adults with: -Reflux oesophagitis. -Gastric and duodenal ulcer -Zollinger-Ellison-Syndrome and other pathological hypersecretory conditions.	40mg per day. Zollinger-Ellison Syndrome 80mg daily. Higher daily doses may be required.	Unlicensed** <u>Severe reflux oesophagitis</u> Intermittent IV Infusion, 0.5–2mg/kg once a day, up to 40mg/day. <u>Active GI bleed</u> Bolus IV Injection 1–2mg/kg (max. 80mg) then continuous IV infusion, 0.1mg/kg/hr (max. 8mg/hr) for a maximum of 3 days.	Reconstituted solution can be administered intravenously over 2 to 15 minutes (as injection or further diluted for infusion)	OR patients on pantoprazole and antiretroviral medicines atazanavir or rilpivirine. In patients taking clopidogrel, pantoprazole may be a better choice of PPI.

Based on most recent versions of the Summary of Product Characteristics on eMC website: www.medicines.org.uk, BNF-C*(lists one generic dose regimen) and Evelina London Paediatric Formulary**, accessed on 18th August 2020

Enquiries

9. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to PharmacyTeam@gov.scot (primary care) or nss.nhssmedicineshortages@nhs.scot (secondary care).