

Guideline for the administration of esomeprazole

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 Publication date: May 2017
 Review date: May 2019
 Version: 1

Introduction

Esomeprazole is a proton pump inhibitor (PPI) used in the management of GORD. It acts by inhibiting gastric acid secretion by blocking the hydrogen-potassium adenosine triphosphatase enzyme system (the 'proton pump') of the gastric parietal cell, thereby reducing the amount of acid in the stomach.

Indication for use

Esomeprazole granules are only to be used in paediatric patients with an enteral feeding tube.

Esomeprazole Injection to be used in paediatric patients only.

Dosage

| Age | Oral (feeding tube)/ IV | Maximum Daily Dose |
|--------------------|-------------------------|--------------------|
| Neonate | 1mg/kg OD | 10mg OD |
| 1month-1yr (<10kg) | 1mg/kg OD | 10mg OD |
| 10-20kg | 10mg OD | 20mg OD |
| >20kg | 10-20mg OD | 40mg OD |

Presentation and Storage

- 10 mg gastro-resistant granules for oral suspension, sachet to be stored at room temperature
- 40 mg powder vial for intravenous injection/infusion. Vial to be stored in outer carton, in order to protect from light, at room temperature

Administration

Granules for administration via an enteral tube (≥French gauge 6):

Add the contents of one sachet to 15ml water and stir until it has dispersed. Draw the required dose into a syringe and inject through the enteral tube immediately after reconstitution. Refill the syringe with water or 0.9% sodium chloride to flush any remaining contents from the enteric tube into the stomach. Any unused suspension should be discarded.

If child fluid restricted please contact pharmacy

Intravenous injection for bolus & infusion:

Reconstitute each 40mg vial with 5mL sodium chloride 0.9%, to give a concentration of 8mg/ml. The reconstituted solution for injection is clear and colourless to very slightly yellow.

As the preparation has a high pH, administer via a central venous catheter device to avoid potential venous irritation. If a central venous access device is unavailable, assess the benefits and risks of peripheral administration for the individual patient (e.g. timeliness of therapy, clinical status of patient). If the peripheral route is used, choose a large vein and monitor the injection site closely using a recognised infusion phlebitis scoring tool.

IV Bolus: Give the required dose by slow IV injection over 3-5 minutes.

The required dose can be given neat from the reconstituted vial, but if necessary, dilute further with sodium chloride 0.9% to ease administration. Maximum concentration 800micrograms/ml.

Short IV infusion: Administer over 10 to 30 minutes.

Dilute the required dose with 50mL sodium chloride 0.9%. To obtain less volume, dilute the reconstituted solution to a concentration not exceeding 800micrograms/ml with sodium chloride 0.9%

See medusa website: homepage ► pharmacy ► injectable medicines guide

Side Effects

Common: Headache, abdominal pain, diarrhoea, and nausea

Less common: Dry mouth, peripheral oedema, dizziness, sleep disturbances, fatigue, paraesthesia, arthralgia, myalgia, rash, pruritus

Very infrequent cases of sub-acute cutaneous lupus erythematosus (SCLE) have been reported in patients taking PPIs. Drug-induced SCLE can occur weeks, months or even years after exposure to the drug. In most cases, symptoms resolve on PPI withdrawal; topical or systemic steroids might be necessary for treatment of SCLE only if there are no signs of remission after a few weeks or months.

Refer to Summary of Product Characteristics for further information

Drug Interactions

Esomeprazole exhibits its mode of action in a similar way to Omeprazole; therefore some drugs noted to interact with Omeprazole can be expected to be have a similar outcome with Esomeprazole.

-Protease inhibitors: Omeprazole has been reported to interact with some protease inhibitors. The clinical importance and the mechanisms behind these reported interactions are not always known. Increased gastric pH during omeprazole treatment may change the absorption of the protease inhibitors. Other possible interaction mechanisms are via inhibition of CYP2C19.

-Methotrexate: When given together with PPIs, methotrexate levels have been reported to increase in some patients. In high-dose methotrexate administration a temporary withdrawal of esomeprazole may need to be considered.

-Tacrolimus: Concomitant administration of esomeprazole has been reported to increase the serum levels of Tacrolimus. A reinforced monitoring of Tacrolimus concentrations as well as renal function (creatinine clearance) should be performed, and dosage of Tacrolimus adjusted if needed.

-Medicinal products with pH dependent absorption: Gastric acid suppression during treatment with esomeprazole and other PPIs might decrease or increase the absorption of medicinal products with a gastric pH dependent absorption. As with other medicinal products that decrease intragastric acidity, the absorption of medicinal products such as ketoconazole, itraconazole and erlotinib can decrease and the absorption of digoxin can increase during treatment with esomeprazole.

- Medicinal products metabolised by CYP2C19: Esomeprazole inhibits CYP2C19, the major esomeprazole metabolising enzyme. Thus, when esomeprazole is combined with medicinal products metabolised by CYP2C19, such as diazepam, citalopram, **imipramine, clomipramine, phenytoin, voriconazole, etc.**, the plasma concentrations of these medicinal products may be increased and a dose reduction could be needed. This should be considered especially when prescribing esomeprazole for on demand therapy.

Refer to Summary of Product Characteristics for more information.

Disposal of waste and Spillage

As per Trust policy for non-cytotoxic waste

References:

- Nexium 10 mg gastro-resistant granules for oral suspension, sachet Summary of Product characteristics, UK. Updated April 2016. Accessed 04.10.16
- Nexium IV 40 mg powder for solution for injection/infusion, Summary of Product characteristics, UK. Updated April 2016. Accessed 04.10.16
- Paediatric Formulary Committee. British National Formulary for Children (online) London: BMJ Group, Pharmaceutical Press, RCPCH and NPPG <<http://www.medicinescomplete.com>> [Accessed on 04.10.16]
- <http://medusa.wales.nhs.uk/IVGuideDisplay.asp> accessed 18/11/2016