הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 05.2013)

תאריך – 7.8.17

שם תכשיר באנגלית ומספר הרישום-

135-56-31128-00

NEXIUM POWDER FOR SOLUTION FOR INJ/INF 40 MG

שם בעל הרישום _אסטרהזניקה ישראל_

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות

טקסט חדש	טקסט נוכחי	פרק בעלון
Interference with laboratory tests Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, esomeprazole treatment should be stopped for at least 5 days before CgA measurements (see section 5.1). If CgA and gastrin levels have not returned to reference range after initial measurement, measurements should be repeated 14 days after cessation of proton pump inhibitor treatment.	Interference with laboratory tests Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, esomeprazole treatment should be stopped for at least 5 days before CgA measurements (see section 5.1).	**4.4 Special Warnings and Special Precautions for Use**
Effects of other drugs on the pharmacokinetics of esomeprazole *Medicinal products which inhibit CYP2C19 and/or CYP3A4* Esomeprazole is metabolised by CYP2C19 and CYP3A4. Concomitant oral administration of esomeprazole and a CYP3A4 inhibitor, clarithromycin (500 mg b.i.d.), resulted in a doubling of the exposure (AUC) to esomeprazole. Concomitant administration of esomeprazole and a combined inhibitor of CYP2C19 and CYP 3A4 may result in more than doubling of the esomeprazole exposure. The CYP2C19 and CYP3A4 inhibitor voriconazole increased omeprazole AUCτ by 280%. A dose adjustment of esomeprazole is not regularly required in either of these situations. However, dose adjustment should be considered in patients with severe hepatic impairment and if	**Effects of other drugs on the pharmacokinetics of esomeprazole** *Medicinal products which inhibit CYP2C19 and/or CYP3A4* Esomeprazole is metabolised by CYP2C19 and CYP3A4. Concomitant oral administration of esomeprazole and a CYP3A4 inhibitor, clarithromycin (500 mg	**4.5 Interaction with other medicinal products and other forms of interaction** **Adverse events**

long-term treatment is indicated. Eye disorders - Blurred vision – uncommon Gastrointestinal disorders - , fundic gland polyps (benign – common General disorders and administration site conditions - increased sweating - rare	b.i.d.), resulted in a doubling of the exposure (AUC) to esomeprazole. The CYP2C19 and CYP3A4 inhibitor voriconazole increased omeprazole AUCτ by 280%. A dose adjustment of esomeprazole is not regularly required in either of these situations. However, dose adjustment should be considered in patients with severe hepatic impairment and if long-term treatment is indicated. Eye disorders - Blurred vision - rare **לא קיים** **לא קיים**	