מאי 2022

רופא/ה, רוקח/ת נכבד/ה
חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

Losec® 20mg
Capsules

לוסק® 20מ"ג
כמוסות

Each capsule contains Omeprazole 20mg

עדכון בעלון לרופא

<u>התוויה כפי שאושרה בתעודת הרישום:</u>

-Acute duodenal ulcer.
-Acute gastric ulcer.
-Helicobacter pylori-associated peptic ulcer disease in combination with antibiotics.
-Reflux esophagitis:
- Treatment ;
- Long-term management;
- Maintenance treatment for the prevention of relapse in patients with severe reflux esophagitis.

-Treatment of severe reflux oesophagitis in children from one year of age and older.
- Maintenance treatment for the prevention of relapse in patients with poorly responsive peptic ulcer.
- Zollinger-ellison syndrome.
- Treatment and prevention of NSAID - associated duodenal and gastric ulcers or erosions in high risk patients.
- Losec 20 mg (OTC): Relief of reflux-like symptoms (e.g. heartburn) with frequency of two or more days a week in sufferers aged 18 and over.

<u>ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות על רקע צהוב, מחיקות מסומנות ע"י קו-חוצה):</u>

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 20 mg omeprazole.
Excipients with known effect: each capsule contains 8 mg lactose and 0.25 mg sodium.

For the full list of excipients, see section 6.1.
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טבע ישראל בע"מ.
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4. CLINICAL PARTICULARS

4.4 Special warnings and precautions for use

Interference with laboratory tests

Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, omeprazole treatment should be stopped for at least 14 days before CgA measurements (see section 5.1). Healthcare providers should temporarily stop omeprazole treatment at least 14 days before assessing CgA levels and consider repeating the test if initial CgA levels are high. If serial tests are performed (e.g. for monitoring), the same commercial laboratory should be used for testing, as reference ranges between tests may vary.

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4.6 Fertility, Pregnancy and lactation

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Fertility

Animal studies with the racemic mixture omeprazole, given by oral administration do not indicate effects with respect to fertility.

4.8 Undesirable effects

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SOC/frequency	Adverse reaction
Metabolism and nutrition disorders:	
Rare:	Hyponatraemia
Not known: ~~Very rare~~	Hypomagnesaemia; severe hypomagnesaemia may result in hypocalcaemia Hypomagnesaemia may also be associated with hypokalaemia.
Gastrointestinal disorders:	
Common:	Abdominal pain, constipation, diarrhoea, flatulence, nausea/vomiting, fundic gland polyps (benign)
Rare:	Dry mouth, stomatitis, gastrointestinal candidiasis
Not known	Microscopic colitis

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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Other effects related to acid inhibition

Decreased gastric acidity due to any means including proton pump inhibitors, increases gastric counts of bacteria normally present in the gastrointestinal tract.

Treatment with acid-reducing drugs may lead to slightly increased risk of gastrointestinal infections such as *Salmonella* and *Campylobacter* and, in hospitalised patients, possibly also *Clostridium difficile*. ~~A diagnosis of Clostridium difficile associated diarrhoea (CDAD) should be considered for patients taking PPIs who develop diarrhoea that does not improve .~~

During treatment with antisecretory medicinal products, serum gastrin increases in response to the decreased acid secretion. Also CgA increases due to decreased gastric acidity. The increased CgA level may interfere with investigations for neuroendocrine tumours. ~~Healthcare providers should temporarily stop omeprazole treatment at least 14 days before assessing CgA levels and consider repeating the test if initial CgA levels are high.~~
Available published evidence suggests that proton pump inhibitors should be discontinued between 5 days and 2 weeks prior to CgA measurements. This is to allow CgA levels that might be spuriously elevated following PPI treatment to return to reference range.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות מאגר התרופות (health.gov.il) **וניתן לקבלו מודפס ע"י פניה לחברת טבע.**

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