

הודעה על החמרה (מידע בטיחות)

תאריך _____ May 29, 2014 _____

שם תכשיר באנגלית _____ **LOSEC Capsules 10 mg, 20 mg** _____

מספרי רישום

10 mg: 128 32 28799 00,-01; 20 mg 050 66 26256 00; 139 78 31879 00, -01 _

שם בעל הרישום _____ Abic Ltd., P.O.Box 8077, Kiryat Nordau, Netanya, Israel

טופס זה מיועד לפרוט החמרות בלבד!

בעלון לרופא

פרטים על השינויים המבוקש/ים

טקסט חדש	טקסט נוכחי	פרק בעלון
<p><i>Interference with laboratory tests</i> Increased CgA level may interfere with investigations for neuroendocrine tumours. To avoid this interference the omeprazole treatment should be stopped for at least 5-14 days before CgA measurements.</p>	<p><i>Interference with laboratory tests</i> Increased CgA level may interfere with investigations for neuroendocrine tumours. To avoid this interference the omeprazole treatment should be stopped for at least 5 days before CgA measurements.</p>	<p>Special warnings and special precautions for use</p>
		<p>Contraindications</p>
		<p>Undesirable effects</p>
		<p>Drug Interactions</p>
		<p>Posology and method of administration</p>
<p>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. Literature reports indicate that proton pump inhibitor treatment should be stopped at least 5-14days before CgA measurement. If CgA and gastrin levels have not normalised after 5-14days, measurements should be repeated 5-14days after cessation of omeprazole treatment.</p> <p>An increased number of ECL cells possibly related to the increased serum gastrin levels, have been observed in some patients (both children and adults) during long term treatment with omeprazole. The findings are considered to be of no clinical significance.</p>	<p>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. Literature reports indicate that proton pump inhibitor treatment should be stopped at least 5 days before CgA measurement. If CgA and gastrin levels have not normalised after 5 days, measurements should be repeated 5 days after cessation of omeprazole treatment.</p> <p>An increased number of ECL cells possibly related to the increased serum gastrin levels, have been observed in some patients (both children and adults) during long term treatment with omeprazole. The findings are considered to be of no clinical significance.</p>	<p>Pharmacodynamic properties</p>

פרטים על השינויים המבוקשים

טקסט חדש	טקסט נוכחי	פרק בעלון
		מתי אין להשתמש בתכשיר
		אין להשתמש בתרופה מבלי להיוועץ ברופא לפני התחלת הטיפול
עלייך ליידע את הרופא במידה והינך עומד לעבור בדיקות מעבדה, יתכן שהרופא יורה לך על הפסקת הטיפול בתכשיר שבועיים לפני הבדיקות.		אזהרות
		תגובות בין-תרופתיות
		נהיגה
		תופעות לוואי
		תופעות לוואי הדורשות התייחסות מיוחדת