# הודעה על החמרה ( מידע בטיחות)

**תאריך** 7.11.11

**שם תכשיר באנגלית:** **Omepradex Caplets 10, 20 & 40 mg**

**מספר רישום** 123 66 30228 ,120 19 30048 00, 123 65 30268 00

**שם בעל הרישום** DEXCEL LTD.

**השינויים בעלון מסומנים ברקע צהוב**

**עלון לרופא**

| פרטים על השינוי/ים המבוקש/ים | | |
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| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **Special warnings and special precautions for use** | … | …<br>Consider PPIs as a possible cause of hypomagnesemia, particularly in patients who are clinically symptomatic. Patients who develop hypomagnesemia may require PPI discontinuation in addition to magnesium replacement. [1]<br>Be aware that consumers either on their own, or based on a healthcare professional's recommendation, may take OTC PPIs for periods of time that exceed the directions on the OTC label. This is considered an off-label (unapproved) use. Healthcare professionals should communicate the risk of hypomagnesemia to patients if they are recommending prolonged use of an OTC PPIs[1].<br>… |
| **Interactions with other medicinal products and other forms of interaction** | … | …<br>*Digoxin*<br>Concomitant treatment with omeprazole (20 mg daily) and digoxin in healthy subjects increased the bioavailability of digoxin by 10%. Digoxin toxicity has been rarely reported. However caution should be exercised when omeprazole is given at high doses in elderly patients. Therapeutic drug monitoring of digoxin should be then be reinforced.<br>Consider obtaining serum magnesium levels prior to initiation of prescription PPI treatment and checking levels periodically thereafter for patients expected to be on prolonged treatment or who take PPIs with medications such as digoxin or drugs that may cause hypomagnesemia (e.g., diuretics). [1]<br>…<br>*Active substances metabolised by CYP2C19:*<br>… |

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| *Cilostazol*[2].<br>Omeprazole, given in doses of 40 mg to healthy subjects in a cross-over study, increased $C_{max}$ and AUC for cilostazol by 18% and 26% respectively, and one of its active metabolites by 29% and 69% respectively [2].<br>…<br>*Unknown mechanism:*<br>…<br>*Diuretics*<br>Hypomagnesemia occurs with both loop diuretics (furosemide, bumetanide, torsemide, and ethacrynic acid) and thiazide diuretics (chlorothiazide, hydrochlorothiazide, indapamide, and metolazone). These agents can cause hypomagnesemia when used as a single agent or when combined with other anti-hypertensives (e.g., beta-blockers, angiotensin receptor blockers and/or ACE inhibitors).[1]<br>… | | |
| …<br>Advise patients to seek immediate care from a healthcare professional if they experience arrhythmias, tetany, tremors, or seizures while taking PPIs. These may be signs of hypomagnesemia.[1]<br>… | … | **Undesirable effects** |
| …<br>Also chromogranin A (CgA) increases due to decreased gastric acidity. The increased CgA level may interfere with investigations for neuroendocrine tumours. To avoid this interference the omeprazole treatment should be temporarily stopped five days before CgA measurements.[2]<br>… | … | **Pharmacodynamic properties** |
| …<br>No metabolite has been found to have any effect on gastric acid secretion. ~~About 80% of the metabolites are excreted in the urine and the rest in the faeces.~~<br>… | …<br>No metabolite has been found to have any effect on gastric acid secretion. About 80% of the metabolites are excreted in the urine and the rest in the faeces.<br>… | **Pharmacokinetic properties** |

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