

הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך: 25.4.2013

שם תכשיר באנגלית ומספר הרישום **Controloc I.V Reg. No. 129-41-30772-00**

שם בעל הרישום : פריגו ישראל סוכנויות בע"מ

טופס זה מיועד לפרוט החמרות בלבד !

החמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p>Hypersensitivity to the active substance, substituted benzimidazoles, or to any of the excipients.</p>	<p>Controloc® I.V. should generally not be used in cases of known hypersensitivity to one of its constituents.</p>	<p>4.3 Contra-indications</p>
<p><i>Hypomagnesaemia</i> Severe hypomagnesaemia has been reported in patients treated with in patients treated with PPIs for at least three months, in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias, and seizures. In most patients, treatment of hypomagnesaemia required magnesium replacement and discontinuation of the PPI.</p>	<p><i>Hypomagnesaemia</i> Hypomagnesaemia, symptomatic and asymptomatic, has been reported rarely in patients treated with PPIs for at least three months, in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias, and seizures. In most patients, treatment of hypomagnesaemia required magnesium replacement and discontinuation of the PPI.</p> <p>For patients expected to be on prolonged treatment or who take PPIs with medications such as digoxin or drugs that may cause hypomagnesaemia (e.g., diuretics), health care professionals may consider monitoring magnesium levels prior to initiation of PPI treatment and periodically.</p>	<p>4.4 Special warnings and special precautions for use</p>

<p><i>Bone fracture</i></p> <p>Proton pump inhibitors, especially if used in high doses and over long durations (>1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognised risk factors. Observational studies suggest that proton pump inhibitors may increase the overall risk of fracture by 10–40%. Some of this increase may be due to other risk factors. Patients at risk of osteoporosis should receive care according to current clinical guidelines and they should have an adequate intake of vitamin D and calcium.</p> <p>Several published observational studies suggest that a proton pump inhibitor (PPI) therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to established guidelines.</p>	<p><i>Bone fracture</i></p> <p>Several published observational studies suggest that proton pump inhibitor (PPI) therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to established guidelines.</p>	
<p>Musculoskeletal and connective tissue disorders:</p> <p>Uncommon: Fracture of the hip, wrist or spine (see section 4.4).</p> <p>Rare: Arthralgia; Myalgia</p>	<p>Musculoskeletal and connective tissue disorders:</p> <p>Rare: Arthralgia; Myalgia</p>	<p>4.8 Undesirable effects</p>