הודעה על החמרה (מידע בטיחות)

תאריך: 26.1.2012

שם תכשיר באנגלית: CONTROLOC IV

מספר רישום: 129.41.30772

שם בעל הרישום: פריגו ישראל סוכנויות בע"מ

השינויים בעלון מסומנים על רקע צהוב

בעלון לרופא:

פרטים על השינוי/ים המבוקש/ים		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
Posology and method of administration		*Hepatic Impairment* A daily dose of 20 mg pantoprazole (half a vial of 40 mg pantoprazole) should not be exceeded in patients with severe liver impairment (see section 4.4).
Contraindications	Pantoprazole, like other PPIs, should not be co-administered with atazanavir.	*(listed under "Warnings")*
Special Warnings and precautions for use	*Listed under Contraindications*	*Co-administration with atazanavir* Co-administration of atazanavir with proton pump inhibitors is not recommended (see section 4.5). If the combination of atazanavir with a proton pump inhibitor is judged unavoidable, close clinical monitoring (e.g virus load) is recommended in combination with an increase in the dose of atazanavir to 400 mg with 100 mg of ritonavir. A pantoprazole dose of 20 mg per day should not be exceeded. *Bone fracture* 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.

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Gastrointestinal infections caused by bacteria Pantoprazole, like all proton pump inhibitors (PPIs), might be expected to increase the counts of bacteria normally present in the upper gastrointestinal tract. Treatment with Controloc may lead to a slightly increased risk of gastrointestinal infections caused by bacteria such as *Salmonella* and *Campylobacter*. *Sodium* This medicinal product contains less than 1 mmol sodium (23 mg) per vial, i.e. is essentially 'sodium-free'.		
Adverse drug reactions such as dizziness and visual disturbances may occur (see section 4.8). If affected, patients should not drive or operate machines.	There are no known effects on the ability to drive and use machines.	**Effects on ability to drive and use of machines**
Metabolism and nutrition disorders - Hyperlipidaemias and lipid increases (triglycerides, cholesterol); weight changes hyponatraemia Psychiatric disorders – sleep disorders, depression (and all aggravations), disorientation (and all aggravations), hallucination; confusion (especially pre-disposed patients, as well as the aggravation of these symptoms in case of pre-existence) Gastrointestinal disorders - abdominal distension and bloating; Hepatobiliary disorders – bilirubin increased Skin and subcutaneous tissue disorders – exanthema / eruption Reproductive system breast disorders – gynaecomastia General disorders – asthenia fatigue and malaise Agranulocytosis Pancytopenia Hypomagnesaemia Taste disorders	triglycerides Psychiatric disorders - Mental depression flatulence	**Undesirable Effects**