הודעה על החמרה (מידע בטיחות)

תאריך: 3.10.2011

שם תכשיר באנגלית: FAVOXIL

מספר רישום: 41-91-25728 ,41-92-25727

שם בעל הרישום : פריגו ישראל פרמצבטיקה בע"מ

השינויים בעלון מסומנים ברקע צהוב

עלון לרופא

פרטים על השינוי/ים המבוקש/ים

טקסט חדש	טקסט נוכחי	פרק בעלון
Fluvoxamine immediate-release tablets should not be used in combination with ramelteon (see section Interaction with other medicinal products). *See Medical Expert Statement (Ramelteon interaction)*		**Contraindications**
Glycaemic control may be disturbed, (i.e., hyperglycemia, hypoglycemia, decreased glucose tolerance), especially in the early stages of treatment. When fluvoxamine is given to patients with a known history of diabetes mellitus, the dosage of anti-diabetic drugs may need to be adjusted. *See Medical Expert statement (Glycaemic Control)*	Glycaemic control may be disturbed, especially in the early stages of treatment. the dosage of anti-diabetic drugs may need to be adjusted.	**Special warnings**
CYP1A2 When given twice daily, 100 mg immediate-release fluvoxamine maleate tablets were administered for 3 days prior to single-dose co-administration of ramelteon 16 mg and immediate-release fluvoxamine maleate tablets, the AUC for ramelteon increased approximately 190-fold and the C_{max} increased approximately 70-fold compared to ramelteon administered alone.		**Drug Interactions**
Epidemiological data have suggested that the use of SSRIs in pregnancy, particularly in late pregnancy, may increase the risk of persistent pulmonary hypertension in the newborn (PPHN). The observed risk was approximately 5 cases	Data on a limited number of exposed pregnancies indicate no adverse effects of fluvoxamine on pregnancy. To date, no other relevant epidemiological data are available.	**Pregnancy and lactation**

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per 1000 pregnancies. In the general population 1 to 2 cases of PPHN per 1000 pregnancies occur. *See Medical Expert Statement (PPHNFU)*		
Endocrine disorders: Hyperprolactinemia, inappropriate antidiuretic hormone secretion *See Medical Expert Statement(Hyperprolactinemia)* Renal and urinary disorders: Micturition disorder (including urinary retention, urinary incontinence, ~~frequency~~ pollakiuria, nocturia and enuresis) *See Medical Expert Statement (Frequency Pollakiuria Replacement)* roductive system and breast disorders: rgasmia, menstrual disorders (such as norrhea, hypomenorrhea, rorrhagia, menorrhagia) *Medical Expert Statement enstrual Disorders)* ss effects: demiological studies, mainly ducted in patients 50 years of age and r, show an increased risk of bone fractures in patients receiving SSRIs and TCAs. The mechanism leading to this risk is unknown. *See Medical Expert Statement (Altered Bone Metabolism)*	Endocrine disorders: inappropriate antidiuretic hormone secretion Renal and urinary disorders: Micturition disorder (including urinary retention, urinary incontinence, frequency, nocturia and enuresis) Reproductive system and breast disorders: Anorgasmia,	**Undesirable effects**
voxamine has a high affinity for a-1 receptors, where it acts as an agonist at therapeutic doses. *See Clincial Expert Statement ma 1 receptor)*		**Pharmacodynamic properties**
Do not store above 25°C. ~~Store in the original package in order to protect from light.~~ *See supportive documentation:* *Storage change Statement April 2011* *Photostability Data 100 mg* *Photostability Data 50 mg*	Do not store above 25°C. Store in the original package in order to protect from light.	**Special precautions for storage**

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פרק בעלון	טקסט נוכחי	טקסט חדש