

## הודעה על החמרה ( מידע בטיחות )

תאריך: 3.1.2012

שם תכשיר באנגלית: TRANDATE INJECTION

מספר רישום: 41-03-23598-21

שם בעל הרישום : פריגו ישראל סוכנויות בע"מ

השינויים בעלון מסומנים על רקע צהוב

בעלון לרופא

פרטים על השינויים המבוקש/ים		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p>The occurrence of Intraoperative Floppy Iris Syndrome (IFIS, a variation of Small Pupil Syndrome) has been observed during cataract surgery in some patients on, or previously treated with, tamsulosin. Isolated reports have also been received with other alpha-1 blockers and the possibility of a class effect cannot be excluded. As IFIS may lead to increased procedural complications during the cataract operation, current or past use of alpha-1 blockers should be made known to the ophthalmic surgeon in advance of surgery.</p> <p>Labetalol need not be discontinued prior to anaesthesia but patients should receive i.v. atropine prior to induction. Labetalol may enhance the hypotensive effects of halothane.</p>		<p>Warnings and precautions</p>