

21st July 2006

**IMPORTANT SAFETY INFORMATION ON INTRAOPERATIVE FLOPPY
IRIS SYNDROME (IFIS) AND TAMSULOSIN**

Dear

Following discussions with the Irish Medicines Board (IMB), Astellas Pharma, wishes to inform you of new safety information regarding the α_1 adrenoceptor antagonist tamsulosin. A known surgical condition, that recently was named "Intraoperative Floppy Iris Syndrome" (IFIS) ¹ has been observed during phacoemulsification cataract surgery in some patients currently or previously treated with tamsulosin. This variant of small pupil syndrome is characterised by the combination of a flaccid iris that billows in response to intraoperative irrigation currents, progressive intraoperative miosis despite preoperative dilation with standard mydriatic drugs, and potential prolapse of the iris toward the phacoemulsification incisions.

Tamsulosin is licensed for the treatment of lower urinary tract symptoms (LUTS) associated with benign prostatic hyperplasia (BPH).

Animal studies in which several α_1 adrenoceptor antagonists (alfuzosin, doxazosin, naftopidil, prazosin, tamsulosin and terazosin) have shown that the α_1 adrenoceptor antagonists tested affect normal iris dilation tone, which might indicate a class effect for this group of drugs ².

At present, the drug most commonly associated with IFIS has been tamsulosin, but IFIS reports, associated with other α_1 adrenoceptor antagonists, have been received.

Discontinuing tamsulosin 1-2 weeks prior to cataract surgery is anecdotally considered helpful, but the benefit and duration of stopping of therapy prior to cataract surgery has not yet been established¹

Initiation of therapy with tamsulosin in patients for whom cataract surgery is scheduled is not recommended.

Any suspected adverse reactions should be notified to the company and /or the IMB, in the usual way

Should you have any questions or require additional information regarding the use of tamsulosin, please contact Dr Greg Hays, Medical Director, Astellas Pharma on 01 467 1555

Yours sincerely



Dr Greg Hays
Medical Director

1. Chang DF, Campbell JR. Intraoperative floppy iris syndrome associated with tamsulosin. J Cataract Refract Surg 2005;31:664-673
2. Michel C. et al. In vivo studies on the effect of α_1 -adrenoceptor antagonists on pupil diameter and urethral tone in rabbits. Naunyn-Schmiedeberg's Arch Pharmacol 2006