

α -1-receptor antagonists (alfusosin, doxazosin, prazosin, tamsulosin, terazosin) and ‘Intraoperative Floppy Iris Syndrome’

as agreed by PhVWP in November 2006

Tamsulosin

Section 4.4: Special warnings and special precautions for use

The ‘Intraoperative Floppy Iris Syndrome’ (IFIS, a variant of small pupil syndrome) has been observed during cataract surgery in some patients on or previously treated with tamsulosin. IFIS may lead to increased procedural complications during the operation. The initiation of therapy with tamsulosin in patients for whom cataract surgery is scheduled is not recommended.

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

During pre-operative assessment, cataract surgeons and ophthalmic teams should consider whether patients scheduled for cataract surgery are being, or have been, treated with tamsulosin in order to ensure that appropriate measures will be in place to manage the IFIS during surgery.

Section 4.8: Undesirable effects

During cataract surgery a small pupil situation, known as Intraoperative Floppy Iris Syndrome (IFIS), has been associated with therapy of tamsulosin during post-marketing surveillance (See also Section 4.4).

Other α -1 adrenoceptor antagonists

SPC wording:

Section 4.4 Special warnings and precautions for use

The ‘Intraoperative Floppy Iris Syndrome’ (IFIS, a variant 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.

PIL wording:

If you are undergoing eye surgery because of cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used xxxxx. This is because xxxxx may cause complications during the surgery which can be managed if your specialist is prepared in advance.