



IMPORTANT DRUG INFORMATION FOR PHYSICIANS

Dear Doctor:

Boehringer Ingelheim
Pharmaceuticals, Inc.

This communication is to inform you of a surgical condition termed Intraoperative Floppy Iris Syndrome (IFIS)¹ that has been observed during phacoemulsification cataract surgery in some patients treated with alpha-1 blockers, including Flomax[®] (tamsulosin HCl). Most of these reports were in patients taking the alpha-1 blocker when IFIS occurred, but in some cases the alpha-1 blocker had been stopped prior to surgery. In most of these cases, the alpha-1 blocker had been stopped recently prior to surgery (2 to 14 days), but in a few cases, IFIS was reported after the patient had been off the alpha-1 blocker for a longer period (5 weeks to 9 months). IFIS is a variant of small pupil syndrome and is characterized 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. Measures such as the utilization of iris hooks, iris dilator rings, or the use of viscoelastic devices such as Healon 5 can minimize the consequences of this syndrome.

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FLOMAX, an alpha-1 blocker indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH), has been commercially available in the United States since 1997.

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Until there is a better understanding of the etiology of this syndrome, it is recommended that male patients being considered for cataract surgery, as part of their medical history, be specifically questioned to ascertain whether they have taken FLOMAX or other alpha-1 blockers. If so, the patient's ophthalmologist should be prepared for possible modifications to their surgical technique that may be warranted should IFIS be observed during the procedure. The benefit of stopping alpha-1 blocker therapy, including FLOMAX, prior to surgery has not been established.

While a definitive causal relationship between IFIS and alpha-1 blockers, including FLOMAX, has not been established, BI has amended the FLOMAX prescribing information to include a reference to IFIS in the **ADVERSE REACTIONS, Post-Marketing Experience** section as well as in the **PRECAUTIONS, General** section.

Attached is the current Prescribing Information for FLOMAX. If you would like further information, please feel free to contact the Boehringer Ingelheim Medical Drug Information Department at (800) 542-6257.

Sincerely,

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References

1. Chang DF, Campbell JR. Surgeons report – a new small pupil syndrome caused by Flomax. *Eye World*. January 2005.