27-JUNE-2016

Direct Healthcare Professional Communication on risk of intraoperative floppy iris syndrome (IFIS) in patients undergoing cataract surgery and taking Calmtrol 0.5, 1, 2, 3, 4 mg FCT.

Dear Healthcare Professional,

Pfizer Saudi Limited would like to inform you that it has been found that RISPERIDONE is associated with a risk of Intraoperative floppy iris syndrome (IFIS), so cataract surgeons should be cautious when doing cataract Surgery while patients are using Risperidone for risk of increased cataract surgery complications. If (IFIS) is suspected, measures to stop the IRIS from prolapsing during cataract operations may be required.

The potential benefit of stopping Risperidone prior to cataract surgery on the risk of IFIS has not been established and must be weighed against the risk of stopping the antipsychotic therapy.

Information on the safety Concern:

Intraoperative floppy iris syndrome (IFIS) is a complication observed during cataract surgery that was first described in 2005 in association with the α1-adrenergic antagonist tamsulosin.1 α 1-adrenergic receptors are present in the iris dilator muscle of the eye, where inhibition of the receptors relaxes this muscle causing a floppy iris and miosis.

IFIS is characterised by a triad of intraoperative signs that may present with varying degrees of severity:

☐ billowing of a flaccid iris stroma
☐ progressive intraoperative pupil constriction
☐ propensity for iris prolapse towards the phaco and side port incisions

Complications of IFIS during cataract surgery include: iris trauma; posterior capsule rupture; and vitreous loss. Postoperative complications include increased intraocular pressure and cystoid macular oedema.
Cases of IFIS associated with the use of antipsychotic agents that have α1-adrenergic receptor-blocking activity have been reported in the literature. Risperidone is an atypical antipsychotic with α1-adrenergic antagonist actions. A review of postmarketing safety data identified six cases of IFIS during cataract surgery reported for Risperidone worldwide. In two of these cases a causal relation between Risperidone and IFIS is plausible. In both these cases, the patients had no history of taking other α1-adrenergic antagonists. Both patients had received long-term treatment with Risperidone and developed typical features of IFIS during cataract surgery. One patient continued treatment with Risperidone and subsequently experienced a second episode of IFIS during cataract surgery on the second eye 4 months later.

The information in this letter has been approved by the Saudi Food and Drug Authority

The Summary of Products Characteristics (SPC) and patient leaflet of **Calmtrol®** (Risperidone) 0.5, 1, 2, 3, 4 mg FCT in Saudi Arabia is updated to reinforce the safety of treated patients.

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the

National Pharmacovigilance and Drug Safety Center (NPC):
By email: npc.drug@sfda.gov.sa
Or by fax: +966 11 2057662
Or by online: https://ade.sfda.gov.sa/

Pharmacovigilance department in the company:

- Email: SAU.AEReporting@Pfizer.com
- Fax: 012 22 93692

Yours sincerely,

Dr. Mohamed Fathy

Pfizer Country Medical Director