

26.12.2013

Risk of Intraoperative Floppy Iris Syndrome (IFIS) related to treatment with risperidone (Ridon®) in patients undergoing cataract surgery.

Dear Healthcare Professional,

Tabuk, in agreement with Saudi Food and Drug Authority wishes to inform you the following:

- There is a risk of intraoperative floppy iris syndrome (IFIS) during cataract surgery in people taking medicine containing risperidone IFIS may increase the risk of eye complications during and after the operation.
- Since IFIS is associated with an increased rate of cataract surgical complications, patients should be specially questioned about current or prior use of risperidone when taking a medication history preoperatively.
- Cataract surgeons should approach surgery with caution in people with such a medication history. If IFIS is suspected, measures to prevent the iris from prolapsing during cataract surgery may be required
- The potential benefit of stopping risperidone before cataract surgery on the risk of IFIS has not been established and must be weighed against the risk of stopping antipsychotic therapy

Further information on the safety concern

Risperidone is an antipsychotic used in the treatment and management of schizophrenia, manic episodes, associated with bipolar disorders and persistent aggression related to psychiatric conditions.

IFIS is an intraoperative complication that has been observed during cataract surgery. It is characterized 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

IFIS is associated with an increased rate of cataract surgical complications (during surgery) including iris trauma; posterior capsule rupture; and vitreous loss. Postoperative complications include increased intraocular pressure and cystoid macular oedema.

Advice for healthcare professionals:

- Primary-care physicians should document the use of α 1-adrenergic antagonists (risperidone) when making a referral for cataract surgery
- When taking a medication history before cataract surgery, patients should be questioned about current or past use of risperidone

Call for reporting:

Please report suspected adverse reactions to the National Pharmacovigilance and Drug Safety Center in Saudi Arabia or Tabuk Pharmaceutical Mfg. Co., addresses are below:

National Pharmacovigilance and Drug Safety Center

Fax: +966-11-205-7662

E-mail: npc.drug@sfda.gov.sa

Website: www.sfda.gov.sa/npc

Suspected adverse reactions should also be reported to Tabuk, phone: +966 11 47 749 46, +966 11 47 826 86, e-mail: botaibi@r.tpmc.com.sa, faisal.alrebeishy@r.tpmc.com.sa

Yours sincerely,



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