8 January 2014

Risk of intraoperative floppy iris syndrome (IFIS) related to treatment with RISPERDAL® (risperidone), RISPERDAL® CONSTA® (risperidone), INVEGA® (paliperidone) in patients undergoing cataract surgery

Dear Healthcare professional,
Janssen would like to inform you of the following:

Summary

This communication is being distributed to alert you to the risk of intraoperative floppy iris syndrome (IFIS) in patients treated with the above medicines during and after cataract surgery.

- IFIS is a recently described intraoperative complication that has been observed during cataract surgery. It is characterised by a triad of intraoperative signs (billowing of a flaccid iris stroma, progressive intraoperative pupil constriction and a propensity for iris prolapse towards the phaco and side port incisions) that may present with varying degrees of severity. IFIS is associated with an increased rate of cataract surgical complications including posterior capsule rupture and vitreous loss.
- If IFIS is suspected, modifications to surgical technique may be required and cataract surgeons need to approach the surgery with caution.
- It is recommended that cataract surgeons ask about current or prior use of the above medicines when taking a medication history preoperatively.
- The estimated reporting frequency of IFIS with risperidone is rare (≥1/10,000 to <1/1,000) based on post-marketing reports. No reports have been received for paliperidone, however the company considers the safety profile qualitatively similar enough to risperidone to warrant inclusion of paliperidone in this notice.
- The following new warning will be included in the Prescribing Information for the above medicines:

  IFIS has been observed during cataract surgery in patients treated with medicines with alpha1a-adrenergic antagonist effect, including Risperdal, Risperdal Consta and INVEGA.

  IFIS may increase the risk of eye complications during and after the operation. Current or past use of medicines with alpha1a-adrenergic antagonist effect should be made known to the ophthalmic surgeon in advance of surgery. The potential benefit of stopping alpha1 blocking therapy prior to cataract surgery has not been established and must be weighed against the risk of stopping the antipsychotic therapy.

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Further information on the safety concern and the recommendations

During routine pharmacovigilance surveillance by the company, an increase in the reporting frequency of IFIS with the use of RISPERDAL was detected. A cumulative review of the company's safety database identified 6 cases of IFIS reported with risperidone. Of the 6 cases, 2 reported a plausible relationship between risperidone treatment and IFIS. In both cases, the patients, who had no history of taking other α 1-adrenergic blockers and received long-term treatment with risperidone, developed typical features of IFIS during the cataract surgery. Symptoms re-occuring on re-administration was demonstrated in one of the two cases where IFIS recurred in the second eye during cataract surgery 4 months later while continuing to take risperidone.

Cases of IFIS associated with the use of antipsychotic agents that have α-adrenergic receptor blocking activity, including risperidone, have been reported in the literature. Risperidone is a selective monoaminergic antagonist with a high affinity for α1-adrenergic receptors; thus, there is a possible biological plausibility of an association with IFIS.

This information has been agreed with the Saudi Food and Drug Authority.

Call for reporting

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