



**JANSSEN
SIN EL-FIL
GENERAL CHEHAB AVENUE
(Near Clinique du Levant)
Beirut-LEBANON**

Malta

August 28th, 2013

Re: Risk of intraoperative floppy iris syndrome (IFIS) related to treatment with risperidone or paliperidone in patients undergoing cataract surgery

Dear Healthcare Professional,

Janssen-Cilag International NV in agreement with the European Medicines Agency and Medicines Authority in Malta would like to inform you of the following:

Summary

- There is a risk of intraoperative floppy iris syndrome (IFIS) during cataract surgery in people taking risperidone (Risperdal, Risperdal Consta; also available as generic) or paliperidone (Invega) or paliperidone palmitate (Xeplion) containing medicines during and after cataract surgery.
- Since IFIS is associated with an increased rate of cataract surgical complications, current or prior use of the above medicines should be asked for when taking a medication history preoperatively.
- Cataract surgeons need to approach surgery with caution. If IFIS is suspected, measures to restrain the iris from prolapsing during cataract surgery may be required.

The Summary of Product Characteristics (SmPC) is being updated for the respective products.

Further information on the safety concern and the recommendations

Risperidone and paliperidone are antipsychotics used in the treatment and management of schizophrenia, manic episodes of bipolar disorders and aggression related to psychiatric conditions.

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

IFIS is associated with an increased rate of cataract surgical complications including posterior capsule rupture and vitreous loss.

Cases of IFIS associated with the use of antipsychotic agents that have α 1-adrenergic receptor blocking activity, including risperidone, have been reported in the literature.

During routine pharmacovigilance surveillance an increase in the reporting frequency of IFIS with the use of risperidone was detected. A cumulative review identified six cases of IFIS reported worldwide with risperidone, two of which reported a plausible relationship between risperidone treatment and IFIS. In both cases, the patients had no history of taking other α 1-adrenergic blockers and received long-term treatment with risperidone and developed typical features of IFIS during the cataract surgery. One of these cases had a positive rechallenge where IFIS recurred in the second eye during cataract surgery 4 months later while continuing to take risperidone.

The estimated reporting frequency of IFIS with risperidone is between 1 in 1,000 and 1 in 10,000 (rare) based on post-marketing reports. No reports have been received for paliperidone, however as this is an active metabolite of risperidone, the information and advice in this letter applies also to paliperidone.

The potential benefit of stopping risperidone or paliperidone 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.

Call for reporting

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefits and risks of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the Medicines Authority. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

Or to

AM Mangion Ltd, N/S off Valletta Road, Luqa LQA 6000, Telephone Number + 356 2397 6333 or on pv@ammangion.com.mt

Communication information

Should you have any questions please contact:

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Yours faithfully,

Hassan Bibi



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