

4th October 2013



## **Risk of intraoperative floppy iris syndrome (IFIS) related to treatment with risperidone, paliperidone or paliperidone palmitate in patients undergoing cataract surgery.**

Dear Healthcare Professional,

Janssen, in agreement with the European Medicines Agency and the Irish Medicines Board, wishes to inform you of the following:

### ***Summary***

- There is a risk of intraoperative floppy iris syndrome (IFIS) during cataract surgery in people taking medicines containing risperidone (Risperdal<sup>®</sup>, Risperdal Consta<sup>®</sup>; also available as generic) or paliperidone (Invega<sup>®</sup>) or paliperidone palmitate (Xeplion<sup>®</sup>). 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 the above medicines 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 Summary of Product Characteristics (SmPC) is being updated for the respective products.

### ***Further information on the safety concern and the recommendations***

Paliperidone is an antipsychotic used in the treatment and management of schizophrenia and manic symptoms of schizoaffective disorder.

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 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  $\alpha$ 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  $\alpha$ 1-adrenergic blockers. Both patients had received long-term treatment with risperidone and developed typical features of IFIS during the cataract surgery. One patient continued treatment with risperidone and subsequently experience a second episode of IFIS during cataract surgery on the second eye 4 months later.

The estimated reporting frequency of IFIS with risperidone is rare (between 1 in 1000 and 1 in 10,000) 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.

Please see the Summary of Product Characteristics on [www.medicines.ie](http://www.medicines.ie) for further information on these medications, [Risperdal<sup>®</sup>, Risperdal Consta<sup>®</sup>, Paliperidone (Invega<sup>®</sup>) or Paliperidone Palmitate (Xeplion<sup>®</sup>)]

### ***Call for reporting***

Reporting suspected adverse reactions after authorisation of a medicinal product is important. It allows continued monitoring of the balance of benefits and risks of the medicinal product.

Please continue to report any suspected adverse drug reactions to the Irish Medicines Board, online at [www.imb.ie](http://www.imb.ie), by e-mail at [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie), telephone 353-1-6764971, fax 353-1-6762517 or by post at 'FREEPOST', Pharmacovigilance Section, Human Products Monitoring Department, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Suspected adverse reactions can also be reported to Janssen on tel: 0044 1494 567 447, fax: 0044 1494 567799 or by e-mail at [dsafety@its.inj.com](mailto:dsafety@its.inj.com)

### ***Company contact point***

If you have further questions, please do not hesitate to contact the Janssen Medical Information team on 1800 709122 or [medinfo@janssen-cilag.co.uk](mailto:medinfo@janssen-cilag.co.uk).

Yours faithfully,



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