

30th July 2010

***Direct Healthcare Professional Communication on the association of silodosin (Urorec)
with Intraoperative Floppy Iris Syndrome (IFIS)***

Summary

This communication is to inform you that silodosin is a new highly selective α 1A-adrenoceptor antagonist that has received a regulatory approval by the EMEA for the treatment of the signs and symptoms of benign prostatic hyperplasia. Silodosin will be marketed in Ireland under the trade name Urorec as from September 1st 2010. Silodosin belongs to the same pharmacological class as tamsulosin, alfuzosin, doxazosin, and terazosin.

A recently diagnosed surgical condition named "Intraoperative Floppy Iris Syndrome" (IFIS) has been observed during cataract surgery in some patients currently or previously treated with tamsulosin, and in rare cases under treatment with other α 1-adrenoceptor antagonists, such as alfuzosin and doxazosin.^{1,2}

One case of IFIS has been observed during the silodosin clinical development program and a total of twelve cases have been reported during the post-marketing experience in Japan since May 2006, indicating that silodosin is also associated with IFIS.

During pre-operative assessment, eye surgeons and ophthalmic teams should consider whether patients scheduled for cataract surgery are being or have been treated with silodosin in order to ensure that appropriate measures are in place to manage IFIS during surgery.

The content of this letter has been agreed with the European Medicines Agency and the Irish Medicines Board.

Further information on IFIS

IFIS is a variant of small pupil syndrome that may lead to increased surgical procedural complications during cataract surgery. It is characterised by the combination of a flaccid iris that billows in response to intraoperative irrigation currents, progressive intraoperative miosis despite pre-operative dilation with standard mydriatic drugs, and potential prolapse of the iris toward the phacoemulsification or side incisions.

Further information on recommendation to healthcare professionals

- Cataract surgeons should ask their patients about past or current use of α -1 adrenoceptor antagonists before surgery
- Initiation of therapy with silodosin is not recommended in patients for whom cataract surgery is scheduled.
- Discontinuing treatment with α 1-adrenoceptor antagonists 2 weeks prior to cataract surgery has been recommended, but the benefit and duration of stopping therapy prior to cataract surgery has not yet been established.

Call for reporting

Please remember that any suspected adverse reactions following the use of Urorec should be reported.

Please use one of the following modalities for reporting to the IMB:

- 1. Online Reporting via the IMB Website www.imb.ie**
- 2. Using post-paid Report Cards (Yellow Cards)**
A supply of cards can be ordered from the IMB:
Tel: (01) 6764971, email imbpharmacovigilance@imb.ie
- 3. Using downloadable form from the IMB website**
A paper adverse reaction form can be downloaded from the IMB Website. This can be sent by Freepost to the IMB.

Adverse reactions following the use of Urorec should also be reported to Recordati Ireland Ltd, Freephone 1800 303351 or via email to medinfo@recordati.co.uk.

Communication information

Should you require further information, please contact Recordati Ireland Ltd., Freephone 1800 303351

References

1. Chang DF, Campbell JR. Intraoperative Floppy Iris Syndrome associated with tamsulosin. J Cataract Refract Surg 2005; 31: 664-73.
2. Neff, KD, Sandoval HP, Fernández de Castro LE et al. Factors associated with Intraoperative Floppy Iris Syndrome. Ophthalmology 2009;116:658-63.