

07-Sept-2015

## **Mirabegron (Betmiga) - new recommendations about the risk of increase in blood pressure**

Dear Healthcare Professional,

In agreement with the European Medicines Agency and the Health Products Regulatory Authority (HPRA), Astellas would like to inform you of new recommendations for the use of Betmiga (mirabegron).

### ***Summary***

- **Serious cases of hypertension and increased blood pressure have been reported in patients on mirabegron treatment.**
- **Mirabegron is now contraindicated in patients with severe uncontrolled hypertension defined as systolic blood pressure  $\geq 180$  mm Hg and/or diastolic blood pressure  $\geq 110$  mm Hg.**
- **Measure blood pressure before starting treatment and monitor it regularly during treatment, especially in patients with hypertension.**

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

Mirabegron is indicated for symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence as may occur in adults with overactive bladder (OAB) syndrome.

Increased blood pressure is a known risk for mirabegron and is included in the product information.

The new recommendations follow a review by the European Medicines Agency of cumulative data associated with mirabegron and increased blood pressure. Serious cases of hypertension and increased blood pressure have been reported in patients on mirabegron treatment.

In addition, there have been some reports of hypertensive crisis and cerebrovascular and cardiac events associated with hypertension with a clear temporal relationship with the use of mirabegron. In some of these cases limited information is provided or other concomitant factors are presented.

Therefore, its use in patients with severe uncontrolled high blood pressure is now contraindicated. Blood pressure should be measured at the start of treatment and monitored regularly, especially in patients with hypertension.

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

As a new active substance authorised in the EU, mirabegron is subject to additional monitoring. This supports enhanced reporting of adverse reactions and allows quick identification of new safety information to further inform safe and effective use.

All suspected adverse reactions associated with mirabegron should be reported in accordance with your national reporting system:

HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2

Suspected adverse reactions should be reported to the HPRA using a Yellow Card obtained either from the HPRA, or electronically via the website at [www.hpra.ie](http://www.hpra.ie). Adverse reactions can also be reported to the HPRA by calling (01) 676 4971.

Reports can be sent either by email or by fax to the Astellas affiliate,  
Email: [irishdrugsafety@astellas.com](mailto:irishdrugsafety@astellas.com)

Tel: 01 467 1555

Fax: 01 467 1550

In order to continue to monitor events associated with increased blood pressure, when reporting such events please provide as much information as possible, including blood pressure measurements.

***Company contact point***

For questions regarding mirabegron and increased blood pressure, please contact Astellas medical information at the following number: 01 467 1555.

Yours sincerely,



**Ralph Nies, MD, MBA**

European Qualified Person for  
Pharmacovigilance



**Martina Dempsey**

Head of Medical  
Astellas Pharma Co Ltd  
5 Waterside,  
Citywest Business Campus,  
Dublin 24