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

Dear Healthcare professional,

In agreement with the European Medicines Agency 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 ≥180 mm Hg and/or diastolic blood pressure ≥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.

You are kindly asked to present reports about all adverse reactions associated with mirabegron to " The Scientific Center of Drug and Medical Technologies Expertise after Emil Gabrielyan" of Ministery of Health of Republic of Armenia.

Address: Komitas ave 49/4, 0051 Yerevan, Republic of Armenia

Tell: + 374 10 23 16 82 * 123, Hot line + 374 10 23 72 65, + 374 98 77 33 68

Web site: www.pharm.am , e-mail: vigilance@pharm.am :

Reports can be sent either by email or by fax to Moscow Representative Office of Astellas Pharma Europe B.V.(Netherlands): see contact details bellow.

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 (Betmiga) and increased blood pressure, please contact Moscow Representative Office of Astellas Pharma Europe B.V.(Netherlands), Russia **Tell:** +7 (495)7370755**, Fax:**+7 (495)7370767

E-mail: Pharmacovigilance.RU@astellas.com

Yours sincerely,

Ralph Nies, MD, MBA	[Add name, titles]
European Qualified Person for Pharmacovigilance	Responsible person e.g. Medical Director, [add name MA-holder]