September 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 Medicines and Healthcare products Regulatory Agency (MHRA), 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.

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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 the MHRA Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼.

It is easiest and quickest to report ADRs online via the Yellow Cards website – https://yellowcard.mhra.gov.uk/.

Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by downloading and printing a form from the website https://yellowcard.mhra.gov.uk/.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name. In order to continue to monitor events associated with increased blood pressure, when reporting such events please also provide blood pressure measurements.

Adverse reactions should also be reported to Astellas Pharma Ltd. either by email to pharmacovigilance.gb@astellas.com or fax to 0203 379 8820.

Company contact point

For questions regarding mirabegron and increased blood pressure, please contact Astellas Medical Information at the following number: 0800 783 5018, or by email to medinfo.gb@astellas.com.

Yours sincerely,

Ralph Nies, MD, MBA

European Qualified Person for Pharmacovigilance

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