This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Mirabegron

March 22, 2016

Non-proprietary name

Mirabegron

Brand name (Marketing authorization holder)

Betanis Tablets 25 mg, 50 mg (Astellas Pharma Inc.)

Indications

Urgency, urinary frequency, and urge urinary incontinence in patients with overactive bladder.

Summary of revision

1. Precautions regarding blood pressure measurement should be newly added in the Important Precautions section
2. “Hypertension” should be newly added in the Clinically significant adverse reaction subsection

Background of the revision and investigation results

The Summaries of Product Characteristics (SPC) have been revised in Europe. In addition, cases of hypertension have been reported in patients treated with mirabegron in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 16 cases* associated with hypertension have been reported (including 7 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

* Cases in which systolic blood pressure greater than or equal to 180 mmHg or diastolic blood pressure greater than or equal to 110 mmHg.

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