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EPAR summary for the public

Betmiga

mirabegron

This is a summary of the European public assessment report (EPAR) for Betmiga. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Betmiga.

What is Betmiga?

Betmiga is a medicine containing the active substance mirabegron. It is available as prolonged-release tablets (25 mg, 50 mg). 'Prolonged-release' means that mirabegron is released slowly from the tablet over a few hours.

What is Betmiga used for?

Betmiga is used in adults with overactive bladder syndrome. It is used to treat certain symptoms of the condition: urgency (sudden urge to urinate), increased urinary frequency (the need to urinate frequently) and urge incontinence (involuntary leakage of urine from the bladder when a sudden strong need to urinate is felt).

The medicine can only be obtained with a prescription.

How is Betmiga used?

The recommended dose of Betmiga is 50 mg once a day. In patients who have reduced kidney or liver function the doctor may need to prescribe a lower dose or avoid the use of Betmiga, especially in patients taking certain other medicines.

For full details, see the package leaflet (also part of the EPAR).

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How does Betmiga work?

The active substance in Betmiga, mirabegron, is a beta-3-adrenergic-receptor agonist. It works by attaching to and activating beta-3 receptors that are found in the muscle cells of the bladder. Experimental studies have shown that, when activated, beta-3 receptors cause the bladder muscles to relax. This is thought to lead to an increase in the capacity of the bladder and changes in the way the bladder contracts, resulting in fewer bladder contractions and thus fewer unwanted urinations.

How has Betmiga been studied?

Betmiga has been studied in three main studies involving 4,611 patients with overactive bladder syndrome. Patients received Betmiga (25 mg, 50 mg or 100 mg) or placebo (a dummy treatment) every day for 3 months. The main measure of effectiveness was the change in the number of urinations and incontinence episodes per day after 3 months of treatment.

What benefit has Betmiga shown during the studies?

Treatment with 50 mg a day of Betmiga was shown to be effective in reducing the number of urination and incontinence episodes. After 3 months of treatment, on average Betmiga 50 mg reduced the number of urinations by 1.8 per day compared with a reduction of 1.2 per day for placebo. Betmiga 50 mg resulted in a reduction of 1.5 incontinence episodes per day compared with a reduction of 1.1 incontinence episodes per day for placebo.

What is the risk associated with Betmiga?

The most common side effects with Betmiga are tachycardia (rapid heartbeat) seen in just over 1 person in 100, and urinary tract infection (infection of the structures that carry urine) seen in just under 3 people in 100. Serious but uncommon side effects include atrial fibrillation (cardiac rhythm disorder). For the full list of all side effects reported with Betmiga, see the package leaflet.

Betmiga must not be used in people who have hypertension (high blood pressure) that is severe and uncontrolled. For the full list of restrictions, see the package leaflet.

Why has Betmiga been approved?

The CHMP noted that the beneficial effects seen with Betmiga were modest but comparable to the benefits of other medicines authorised for this condition. Regarding its safety, most side effects are comparable to those of other medicines used for treating overactive bladder syndrome. The potential risk of hypersensitivity (allergic reactions) and effects on the heart has been adequately addressed in the product information. The CHMP therefore decided that Betmiga's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Betmiga?

A risk management plan has been developed to ensure that Betmiga is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Betmiga, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Betmiga

The European Commission granted a marketing authorisation valid throughout the European Union for Betmiga on 20 December 2012.

The full EPAR for Betmiga can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Betmiga, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 09-2015.