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Betmiga (*mirabegron)*

An overview of Betmiga and why it is authorised in the EU

What is Betmiga and what it is used for?

Betmiga is a medicine 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).

Betmiga is also used in children and adolescents, aged from 3 to less than 18 years, to treat neurogenic detrusor overactivity (NDO). NDO is a condition where the bladder is overactive caused by the nerves not communicating correctly with the bladder muscles.

Betmiga contains the active substance mirabegron.

How is Betmiga used?

Betmiga can only be obtained with a prescription and is available as prolonged-release tablets and as prolonged-release granules that are used to make a suspension that is taken by mouth. 'Prolonged-release' means that mirabegron is released slowly from the tablet or granules over a few hours.

Betmiga is taken once a day. In children, the dose and form taken depends on the patient's body weight. 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 more information about using Betmiga, see the package leaflet or contact your doctor or pharmacist.

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. 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 urination episodes.

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What benefits of Betmiga have been shown in studies?

Adults

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

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

Children

A study involving 86 children and adolescents aged from 3 to less than 18 years with NDO showed that after 24 weeks of treatment, on average patients had an increase in the maximum cystometric capacity (MCC) of around 87 millilitres (mL). MCC is a measure of the largest volume of urine that the bladder can store comfortably before there is a strong need to urinate. The study did not compare Betmiga with other medicines or placebo.

What are the risks associated with Betmiga?

For the full list of side effects and restrictions with Betmiga, see the package leaflet.

The most common side effects with Betmiga in adults (which may affect up to 1 in 10 people) include tachycardia (rapid heartbeat) and urinary tract infection (infection of the structures that carry urine). Serious but uncommon side effects include atrial fibrillation (cardiac rhythm disorder).

Overall, the safety profile in children and adolescents is similar to that seen in adults. The most common side effects with Betmiga in children include urinary tract infection, constipation and nausea (feeling sick).

Betmiga must not be used in people who have hypertension (high blood pressure) that is severe and uncontrolled.

Why is Betmiga authorised in the EU?

The European Medicines Agency considered that the beneficial effects seen with Betmiga in adults were modest but comparable to the benefits of other medicines authorised for the treatment of overactive bladder syndrome.

Betmiga was also shown to control bladder activity in children and adolescents aged from 3 to less than 18 years with NDO. Although there were some limitations in the main study in children, such as the small number of patients involved in the study, the lack of a comparator and limited data on the long-term effects in these patients, treatment with Betmiga was shown to improve the bladder's ability to store urine. The treatment effect was in line with that reported in published studies with other medicines commonly used to treat NDO.

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 have been adequately addressed in the product information.

The European Medicines Agency therefore decided that Betmiga's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Betmiga have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Betmiga are continuously monitored. Side effects reported with Betmiga are carefully evaluated and any necessary action taken to protect patients.

Other information about Betmiga

Betmiga received a marketing authorisation valid throughout the EU on 20 December 2012.

Further information on Betmiga can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/betmiga.

This overview was last updated in 07-2024.