



Midlands and Lancashire Commissioning Support Unit

Prescribing Tip No. 184 Date: 24th November 2017

Mirabegron (Betmiga ▼): risk of severe hypertension and associated cerebrovascular and cardiac events

Mirabegron (Betmiga ▼) is a beta 3-adrenoceptor agonist used in the management of urinary frequency, urgency, and incontinence in overactive bladder syndrome.

RAG GREEN Medicines Mirabegron is rated on the Lancashire Management Group website (http://www.lancsmmg.nhs.uk/medicines/mirabegron/) and for Greater Preston, Chorley & South Ribble CCG's it is restricted to third line use as per NICE TA 290. Mirabegron is recommended as an option for treating the symptoms of overactive bladder only for people in whom antimuscarinic drugs are contraindicated or clinically ineffective, or have unacceptable side effects.

The MHRA¹ has reported a recent EU-wide review of the latest safety data for mirabegron. This has led to new measures to help reduce the risks of severe hypertension. It is already known that mirabegron can increase blood pressure. However, cases of severe hypertension have been reported, which include hypertensive crisis associated with reports of cerebrovascular and cardiac events (mainly transient ischaemia attack or stroke) — some with a clear temporal relation to mirabegron use.

- Mirabegron is now contraindicated in patients with severe uncontrolled hypertension; (systolic blood pressure ≥180 mm Hg or diastolic blood pressure ≥110 mm Hg, or both). Regular monitoring of blood pressure is important, especially in patients with pre-existing hypertension.
- Data are limited regarding use of mirabegron in patients with stage 2 hypertension (i.e. systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg) and it should therefore be used with caution in this group.

Advice for prescribers:

- Mirabegron is contraindicated in patients with severe uncontrolled hypertension (systolic blood pressure ≥180 mm Hg or diastolic blood pressure ≥110 mm Hg, or both).
- Blood pressure should be measured before starting treatment and monitored regularly during treatment, especially in patients with hypertension
- Please report suspected side effects to mirabegron on a <u>Yellow Card</u>

Ref. 1 https://www.gov.uk/drug-safety-update/mirabegron-betmiga-risk-of-severe-hypertension-and-associated-cerebrovascular-and-cardiac-events

To contact the Medicines Optimisation Team please phone 01772 214302



