PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Betmiga 25 mg prolonged release film coated tablet
Betmiga 50 mg prolonged release film coated tablet
Mirabegron

Sugar free

Read all of this leaflet carefully before you start taking Betmiga

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Betmiga has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1 What Betmiga is and what it is used for

Betmiga contains the active substance mirabegron. It is a bladder muscle relaxant (a so-called beta 3-adrenoceptor agonist), which reduces the activity of an overactive bladder and treats the related symptoms.
Betmiga treats the symptoms of an overactive bladder such as:
- suddenly needing to empty your bladder (called urgency).
- having to empty your bladder more than usual (called increased urinary frequency).
- not being able to control when you empty your bladder (called urgency incontinence).

2 What you need to know before you take Betmiga

Do not take Betmiga:

- if you are hypersensitive (allergic) to mirabegron (active substance) or any of the other ingredients of Betmiga (listed in section 6).
- if you have severe kidney disease (severe end-stage renal impairment).
- if you have severe liver disease (severe hepatic impairment).
- if you have uncontrolled high blood pressure.

Warnings and precautions

Talk to your doctor or pharmacist before taking Betmiga:
- if you have trouble emptying your bladder or you have a weak urine stream or if you take other medicines for the treatment of overactive bladder such as anticholinergic medicines.
- if you have kidney or liver problems, your doctor may need to reduce your dose or may tell you not to take Betmiga, especially if you are taking other medicines such as itraconazole, ketoconazole (fungal infections), ritonavir (HIV/AIDS) or

clarithromycin (bacterial infections). Tell your doctor about the medicines that you take.
- if you have an ECG (heart tracing) abnormality or you are taking any medicine known to cause an abnormal ECG such as:
    - medicines used for abnormal heart rhythm such as quinidine, sotalol, procainamide, ibutilide, flecainide, dofetilide, and amiodarone;
    - medicines used for allergic rhinitis;
    - antipsychotic medicines (medicines for mental illness) such as thioridazine, mesoridazine, haloperidol, and chlorpromazine;
    - anti-infectives such as pentamidine, moxifloxacin, erythromycin, and clarithromycin.

Betmiga may cause your blood pressure to increase or make your blood pressure worse if you have a history of high blood pressure. It is recommended that your doctor check your blood pressure while you are taking Betmiga.

Children and adolescents

Do not give Betmiga to children and adolescents under the age of 18 years because the safety and efficacy in this age group has not been established.

Other medicines and Betmiga

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines.)
- Tell your doctor if you take propafenone (used for treating certain types of irregular heartbeats), thioridazine (used in the treatment of schizophrenia), or flecainide (used for treating certain types of irregular heartbeats).
- Tell your doctor if you take digoxin. Blood levels of digoxin can be checked by your doctor. If the blood level is out of range, your doctor may need to adjust the dose of digoxin.

Pregnancy and Breastfeeding:

You should not take Betmiga if you are pregnant, are planning to become pregnant or are breastfeeding your baby. It is likely that Betmiga passes into your breastmilk. You and your doctor should decide if you will take Betmiga or breastfeed. You should not do both.

Driving and using machinery:

Betmiga may cause drowsiness, dizziness or blurred vision affecting your ability to drive or use machines.

3 How to take Betmiga

Do not share medicines prescribed for you with any other person.
Always take Betmiga exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
The usual dose is one 50 mg Betmiga tablet by mouth once daily. If you have kidney or liver problems, your doctor may need to reduce your dose to one 25 mg Betmiga tablet by mouth once daily. You should take Betmiga with liquids and swallow the tablet whole.

Do not crush or chew the tablet.
Betmiga can be taken with or without food.

Your doctor will tell you how long your treatment with Betmiga will last.
Do not stop treatment with Betmiga early if you do not see an immediate effect. Your bladder might need some time to adapt. You should continue taking your tablets. Do not stop taking them when your bladder condition improves. Stopping treatment may result in recurrence of symptoms of overactive bladder.
If you have the impression that the effect of Betmiga is too strong or too weak, tell your doctor or pharmacist.

If you take more Betmiga than you should:

If you have taken more tablets than you have been told to take, or if someone else accidentally takes your tablets, contact your doctor, pharmacist or hospital for advice immediately.
Symptoms of overdose may include a forceful beating of the heart, an increased pulse rate or an increased blood pressure.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take / missed a dose of Betmiga:

If you forget to take your medicine, take the missed dose as soon as you remember, unless it is 6 hours or less before your next scheduled dose. Then continue to take Betmiga at the usual time.
Do not take a double dose to make up for a forgotten dose. If you miss several doses, tell your doctor and follow the advice given to you.

If you stop taking Betmiga:

Do not stop taking Betmiga without talking to your doctor first, as your overactive bladder symptoms may come back.

4 Possible side effects

Betmiga can have side effects.
Not all side effects reported for Betmiga are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking Betmiga and tell your doctor immediately or go to the casualty department at your nearest hospital:
A serious side effect is swelling of the deeper layers of the skin caused by a build-up of fluid, which can affect any part of the body including the face, tongue or throat and may cause difficulty in breathing (angioedema).

The most serious side effects include irregular heart beat (atrial fibrillation). This is a less frequent side effect (may affect up to 1 in 100 people), but if this side effect occurs, immediately stop taking Betmiga and seek urgent medical advice.

If you get headaches, especially sudden, migraine-like (throbbing) headaches, tell your doctor. These may be signs of severely elevated blood pressure.

Frequent side effects
- Increased heart rate (tachycardia)
- Urinary tract infection
- Nausea
- Constipation
- Headache
- Diarrhoea
- Dizziness

Less frequent side effects
- Hypertensive crisis
- Increased blood pressure
- Feeling your heartbeat (palpitations)
- Increase in liver enzymes (increased GGT, increased AST, increased ALT) determined by blood tests.
- Bladder infection (cystitis)
- Vaginal infection
- Indigestion (dyspepsia)
- Infection of the stomach (gastritis)
- Swelling of the joints
- Itching of the vulva or vagina (vulvovaginal pruritus)
- Itching, rash or hives (urticaria, macula rash, papular rash, pruritus)
- Swelling of the eyelid (eyelid oedema)
- Swelling of the lip (lip oedema)
- Small purple spots on the skin (purpura)
- Inflammation of small blood vessels mainly affecting the skin (leukocytoclastic vasculitis)
- Inability to completely empty the bladder (urinary retention)
- Insomnia

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.
Or
Astellas Pharma (Pty) Ltd, 7 Mirage Road, Bedfordview, 2007, South Africa
Tel: +27 11 615 9433 Fax: +27 11 615 9427
Drugsafety.za@astellas.com
By reporting side effects, you can help provide more information on the safety of Betmiga.

5 How to store Betmiga

Store all medicines out of reach of children.
- Do not use Betmiga after the expiry date which is stated on the carton or blister pack. . The expiry date refers to the last day of that month.
- Do not remove the tablet from the blister until required for use.
- Store at or below 25°C.
- Return all unused medicine to your pharmacist.

- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6 Contents of the pack and other information

What Betmiga contains

The active substance is mirabegron.
Betmiga 25 mg prolonged-release tablets
Each tablet contains 25 mg of mirabegron.
Betmiga 50 mg prolonged-release tablets
Each tablet contains 50 mg of mirabegron.
- The other ingredients are:
Tablet core: Macrogols, hydroxypropylcellulose, butylhydroxytoluene, magnesium stearate
Film-coating: Hypromellose, macrogol, iron oxide yellow (E172), iron oxide red (E172) (25 mg tablet only).

What Betmiga looks like and contents of the pack

Betmiga 25 mg prolonged release film-coated tablets are oval, brown film coated tablets, debossed with the company logo and “325” on the same side.
Betmiga 50 mg prolonged release film-coated tablets are oval, yellow film coated tablets, debossed with the company logo and “355” on the same side.

Betmiga 25 mg tablets and Betmiga 50 mg tablets are packed in aluminium-aluminium blisters (Polyamide/Aluminium/PVC laminate foil sealed with an aluminium foil/heat seal coated lidding foil) in cartons containing 30 tablets.

Holder of Certificate of Registration

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BETMIGA 50 mg: 47/16.5/0298

Access to the corresponding Professional Information

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