

BETMIGA®

(BET-mee-ga)

Mirabegron (my-ra-BEG-ron)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about BETMIGA.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking BETMIGA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What BETMIGA is used for

BETMIGA contains mirabegron, a beta 3-adrenoceptor agonist, which is used to treat symptoms of an overactive bladder.

Overactive bladder occurs when you cannot control your bladder contractions. When these muscle contractions happen too often or cannot be controlled, you can get symptoms such as:

- suddenly needing to empty your bladder (urgency)
- having to empty your bladder more than usual (increased urinary frequency)
- not being able to control when you empty your bladder (urgency incontinence).

BETMIGA works by reducing the activity of an overactive bladder and treats the related symptoms.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is only available with a doctor's prescription.

The safety and effectiveness of BETMIGA in children and adolescents under the age of 18 years have not been established.

There is no information to suggest that BETMIGA affects your ability to drive or use machinery. Be careful driving or operating machinery until you know how BETMIGA affects you. It may cause dizziness in some people. If this occurs, do not drive or use machinery.

Before you take BETMIGA

When you must not take it

Do not take BETMIGA if you have an allergy to:

- any medicine containing mirabegron
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take BETMIGA if you have very high blood pressure (systolic greater than

or equal to 180mmHg and /or diastolic greater than or equal to 110mmHg).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems
- high blood pressure
- heart disorders, including an irregular heartbeat, an abnormal electrical signal in the heart that can cause an irregular heart rhythm called "prolongation of the QT interval", or if you are taking any medicine known to cause irregular heart rhythm (see 'Taking other medicines')
- trouble emptying your bladder or you have a weak urine stream

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking BETMIGA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and BETMIGA may interfere with each other. These include:

- thioridazine (a medicine for mental illness), propafenone or flecainide (medicines for abnormal heart rhythm), metoprolol (a medicine for high blood pressure or heart problems), imipramine or desipramine (medicines used for depression). These specific medicines may require dose adjustment by your doctor.
- some anti-fungal medicines (e.g. itraconazole, ketoconazole)
- ritonavir (a medicine used to treat HIV/AIDS)
- digoxin (a medicine for heart failure or abnormal heart rhythm). Blood levels of digoxin are measured by your doctor. If the blood level is out of range, your doctor may adjust the dose of digoxin
- medicines used for the management of overactive bladder (e.g. solifenacin, tolterodine, oxybutynin, darifenacin, trospium, fesoterodine) and medicines used for the management of enlarged prostate (e.g. tamsulosin)

- some medicines that are known to prolong QT interval, such as quinidine, sotalol, amiodarone (medicines used for abnormal heart rhythm), mesoridazine, haloperidol (medicines for mental illness), or erythromycin, clarithromycin (anti-infectives)

These medicines may be affected by BETMIGA or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take BETMIGA

Follow directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual dose is 25 mg tablet once a day. Based upon your response and tolerability, your doctor may increase your dose to 50 mg once daily. The maximum dose for BETMIGA is 50 mg once daily.

How to take it

Swallow the tablet whole with a full glass of water. Do not crush or chew the tablet.

You can take the tablet with or without food.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Do not stop treatment with BETMIGA early if you do not see an immediate effect. Your bladder might need some time to adapt.

Do not stop taking BETMIGA when your bladder condition improves.

This medicine helps to control your condition, but does not cure it. Stopping treatment may result in a recurrence of symptoms of an overactive bladder.

If you forget to take it

If it is 6 hours or less before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much BETMIGA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much BETMIGA, you may feel a fast heart rate.

While you are using BETMIGA

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking BETMIGA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take BETMIGA to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or alter the dosage without checking with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking BETMIGA.

This medicine helps most people with overactive bladder but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- indigestion (dyspepsia)
- common cold symptoms (nasopharyngitis)
- headache
- dizziness
- nausea (feeling sick) or vomiting
- fatigue
- constipation
- stomach, back or joint pain
- urinary tract infection, including signs such as burning or pain when passing urine, or an urge to pass urine frequently. Urine may have a strong smell, looks cloudy or contains blood
- vaginal discharge, itching or burning
- increased blood pressure

- increase in liver enzymes

Tell your doctor as soon as possible if you notice any of the following:

- fast or irregular heartbeats
- swelling of the face, eyelid, lips, tongue, throat, airways or joints
- rash, itchiness or hives

The above list includes serious side effects that may require medical attention.

If swelling involves the tongue, throat or airways seek medical attention immediately.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some of these side effects (for example, changes in blood test results, blood pressure or liver enzymes) can only be found when your doctor does tests from time to time to check your progress.

After using BETMIGA

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store BETMIGA or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

BETMIGA is available in 25 mg or 50 mg strengths:

25 mg tablet is an oval, brown film-coated tablet, debossed with the (Astellas logo) and "325"

50 mg tablet is an oval, yellow film-coated tablet, debossed with the (Astellas logo) and "355"

Both strengths are available in packs of 30 tablets.

Ingredients

BETMIGA contains 25 mg or 50 mg of mirabegron as the active ingredient.

The tablets also contain:

- macrogol 8000
- macrogol 2000000
- hypolose
- purified water
- butylated hydroxytoluene
- magnesium stearate
- OPADRY complete film coating system 03F43159 ORANGE (25 mg tablet only)

- OPADRY complete film coating system 03F42192 YELLOW (50 mg tablet only).

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

BETMIGA is supplied in Australia by:

Astellas Pharma Australia Pty Ltd
6 Eden Park Drive
Macquarie Park, NSW 2113

Medical Information:
1800 751 755

® = Registered Trademark

Australian Registration Numbers

- 25 mg tablet: AUST R 199664
- 50 mg tablet: AUST R 199668

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