Package leaflet: information for the user
Betmiga 25 mg prolonged-release tablets
Betmiga 50 mg prolonged-release tablets
mirabegron

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may be harmful to others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect that is not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Betmiga and what is this medicine used for?
Betmiga contains the active substance mirabegron. The medicine is a bladder muscle relaxant (a so-called beta-3 adrenoceptor agonist), which reduces the activity of an overactive bladder and the associated treats symptoms and reduces neurogenic overactivity of the detrusor muscle.

Betmiga is used for:
- the treatment of the symptoms of a condition called overactive bladder in adults. These symptoms include among others:
  sudden strong urge to urinate ('urgency' called);
  more frequent need to urinate more than usual ('frequent urination');
  your unable to hold your urine ('urge incontinence').
- the treatment of a condition called neurogenic detrusor overactivity in children from 3 to under 18 years. Neurogenic detrusor overactivity is a condition where involuntary bladder contractions occur due to a condition you were born with, or injury to the nerves that control the bladder. If untreated, neurogenic detrusor overactivity can lead to damage to your bladder and/or kidneys. Betmiga is used to is used to to increase the amount of urine your bladder can hold and reduce urine leakage.

2. When should you not take this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in
- section 6. section 6.
- When should you be extra careful with this medicine?

When should you be extra careful with this medication?
Contact your doctor or pharmacist before taking this medicine:

- if you have difficulty emptying your bladder or have a weak urine stream or if you are taking other medicines for the treatment of an overactive bladder or neurogenic detrusor overactivity, such as anticholinergic medicines.-
- if you have kidney or liver problems. Your doctor may need to lower your dose or advise you not to take Betmiga , especially if you are taking other medicines such as itraconazole, ketoconazole (for fungal infections), ritonavir (for HIV/AIDS), or clarithromycin (for bacterial infections). Inform your doctor about the medicines you are using.
- if you have an abnormality on an ECG (heart tracing) called QT prolongation or if you are taking a medicine known to cause QT prolongation such as:
  - o medicines used for an abnormal heart rhythm, such as quinidine, sotalol, procainamide, ibutilide, flecainide, dofetilide and amiodarone;
  - o medicines used for allergic rhinitis (inflammation of the nasal mucosa);
  - o antipsychotics (medicines for mental disorders), such as thioridazine, mesoridazine, haloperidol and chlorpromazine;
  - o anti-infectives, such as pentamidine, moxifloxacin, erythromycin and clarithromycin.

Betmiga can increase your blood pressure or worsen your blood pressure if you have a history of high blood pressure. It is recommended that your doctor monitors your blood pressure while you are using this medication.

Children and adolescents under 18 years
This medication should not be given to children and adolescents under 18 years for the treatment of an overactive bladder. This is because the safety and efficacy of

Betmiga in this age group have not been established.
Betmiga should not be used in children under 3 years for the treatment of neurogenic detrusor overactivity.

Are you taking any other medications?
Are you using any other medications besides Betmiga , have you done so recently , or is there a possibility that you will use other medications soon? If so, tell your doctor or pharmacist.

Betmiga can affect the action of other medications, and other medications can affect the action of this medication.

- Tell your doctor if you are using thioridazine (a medication for mental disorders), propafenone of flecainide (medicines for an irregular heartbeat), imipramine or desipramine (medicines for depression). It may be necessary for your doctor to adjust the dose of these specific medicines.
- Tell your doctor if you are using digoxin (a medicine for heart failure or an irregular heartbeat). The blood concentration of this medicine is measured by your doctor. If the

blood concentration is outside the normal range, your doctor may adjust the dose of digoxin.
- Tell your doctor if you are using dabigatran etexilate (a medicine used to reduce the risk of blood vessel blockage in the brain or body due to blood clot formation in patients with an irregular heartbeat (called atrial fibrillation) in conjunction with other risk factors). It may be necessary for your doctor to adjust the dose of this medicine.

Pregnancy and breastfeeding
Are you pregnant, do you think you might be pregnant, or do you want to become pregnant? Then you must not take Betmiga do not take.

Are you breastfeeding? Then contact your doctor or pharmacist before taking this medicine. This medicine is likely to pass into your breast milk. You should decide with your doctor whether to take Betmiga or to breastfeed. You must not do both.

Driving and using machines
There is no information to suggest that this medicine affects your ability to drive or your ability to operating machinery.

3. How do you take this medicine?

Always take this medicine exactly as your doctor has told you. Are you unsure about the correct usage? Then contact your doctor or pharmacist.

Use in adults with an overactive bladder
The recommended dosage is one 50 mg tablet once daily by mouth. If you have kidney or liver problems, your doctor may need to reduce your dose to one 25 mg tablet once daily by mouth. You should take this medicine with liquid and swallow the tablet whole. You must not crush or chew the tablet. Betmiga Betmiga Use in children and adolescents (aged 3 to under 18 years) with neurogenic

detrusor overactivity
Take this medicine once daily by mouth. You should take this medicine with liquid

and swallow the tablet whole. You must not crush or chew the tablet. Take and swallow the tablet whole. You must not crush the tablet or chew it. Betmiga take. Your doctor will calculate the correct dose for a patient, depending on his or her body weight. body weight. You must carefully follow your doctor's instructions.

Have you taken too much of this medicine?

If you have taken more tablets than prescribed or if someone else accidentally takes your tablets, you should immediately contact your doctor, pharmacist, or hospital for advice.

Symptoms of overdose include pounding heart, increased heart rate, and increased blood pressure.

Have you forgotten to take this medicine?
If you have forgotten to take this medicine, you should take the missed dose as soon as you remember. If this is less than 12 hours before your next scheduled dose, skip the dose and then take your medicine at the usual time.

Do not take a double dose to make up for a forgotten dose. If you miss multiple doses, you should tell your doctor and follow the advice given to you.

If you stop taking this medicine
Do not stop treatment with Betmiga prematurely if you do not notice an immediate effect. Your bladder may need some time to adjust. You should continue taking your tablets. Do not stop taking them if your bladder problem improves. Stopping the treatment may cause the symptoms of an overactive bladder or neurogenic detrusor overactivity return.

Do not stop using Betmiga without first talking to your doctor, as your symptoms of an overactive bladder or neurogenic detrusor overactivity may return.

Do you have any other questions about the use of this medicine? Then contact yourdoctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can have side effects, although not everyone gets them. to make.

heartbeat atrial fibrillation). This). This this side effect occurs, you should stop using the medicine immediately and seek medical advice. If you get a headache, especially a sudden one,

If you experience a headache, especially a sudden one, migraine-like (throbbing) headache, you should inform your doctor. These may be signs of a severe increase in blood pressure.

Other possible side effects include:
Common (occur in less than 1 in 10 users)

- Infection of the urinary tract (urinary tract infections)
- Headache

- Dizziness
- Accelerated heartbeat (tachycardia)
- Nausea
- Constipation (constipation)
- Diarrhea

Sometimes (occur in less than 1 in 100 users)
- Vaginal infection
- Bladder infection (cystitis)
- Clearly palpable heartbeat (palpitations)
- Irregular heartbeat (atrial fibrillation)
- Digestive complaints (dyspepsia)
- Inflammation of the stomach (gastritis)
- Itching, rash or hives (urticaria, rash, blotchy rash, papular rash,
- pruritus)
- Swelling of the joints
- Itchy vulva or vagina (vulvovaginal pruritus)
- Increased blood pressure
- Increased liver enzymes (GGT, AST, and ALT)

Rare (occur in less than 1 in 1,000 users)
- Swelling of the eyelids (eyelid edema)
- Swelling of the lips (lip edema)
- Inflammation of blood vessels, mainly of the skin (leukocytoclastic vasculitis)
- Small purple spots on the skin (purpura)
- Swelling of the deeper layers of the skin caused by fluid accumulation, which can occur anywhere on the body, including the face, tongue, or throat, and can cause difficulties cause when breathing (angioedema)
- Inability to completely empty the bladder (urinary retention)

Very rarely (occurs in less than 1 in 10,000 users)
- Severely high blood pressure (hypertensive crisis)

Not known (cannot be determined from the available data)
- Insomnia
- Confusion

Betmiga may increase the risk of being unable to empty your bladder if you have an obstruction (narrowing) of the bladder outlet or if you are using other medications for the treatment of an overactive bladder. Contact your doctor immediately if you are unable to empty your bladder.

Reporting side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as mentioned in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?
Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You will find it on the box or on the blister pack after EXP. It states a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. If you dispose of medicines in the correct way, they are destroyed responsibly and do not enter the environment. correct.

6. What substances are in this

medicine?- --

- mirabegron Betmiga.
  Each tablet contains 25 mg mirabegron
  Each tablet contains 25 mg Betmiga.
  Betmiga 50 mg extended-release tablets
  Each tablet contains 50 mg mirabegron.
- The other ingredients in this medicine are:
  Tablet core: macrogols, hydroxypropylcellulose, butylated hydroxytoluene, magnesium stearate Film coating: hypromellose, macrogol, yellow iron oxide (E172), red iron oxide (E172) (only for 25 mg tablet).

What does Betmiga look like and how many are in a package?

Betmiga 25 mg film-coated extended-release tablets are oval, brown film-coated tablets, marked with the company logo and '325' on the same side.

Betmiga 50 mg film-coated extended-release tablets are oval, yellow film-coated tablets, marked with the company logo and '355' on the same side.

Betmiga is available in aluminum-aluminum blister packs in packages containing 10, 20, 30, 50, 60, 90, 100, or 200 tablets.

Not all pack sizes may be available in your country.

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Manufacturer
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More information about this medicine is available on the website of the European Medicines Agency: https://www.ema.europa.eu