**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'**

**REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

**Betmiga 25mg**

***Prolonged-release tablets***

**Betmiga 50mg**

***Prolonged-release tablets***

**Composition:**
Each tablet of Betmiga 50mg contains: Mirabegron 50 mg.
Each tablet of Betmiga 25mg contains: Mirabegron 25 mg.

**Excipients** - see section 6 "Additional Information"

**Please read the leaflet carefully in its entirety before using the medicine**.
This leaflet contains concise information about the medicine. If you have further questions, please ask the physician or the pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar. The medicine is not intended for children under the age of 18 as the safety and efficacy of Betmiga was not established in this age group.

## 1. What is the medicine intended for?

The medicine is meant for treatment of symptoms of an overactive bladder.

**Therapeutic group**: Beta-3-adrenoreceptor agonist.

## 2. Before using the medicine.

**Do not use the medicine:**

- If you have hypersensitivity (allergy) to the active substance or any of the additional components which the medicine contains (see section 6).
- if you have very high uncontrolled blood pressure

**Special warnings regarding use of the medicine:**

Consult your physician before starting of treatment**:**

- If you have difficulties in emptying your bladder, if you have weak urine stream or if you take other medicines for the treatment of an overactive bladder such as anticholinergic medicines.
- If you have abnormal liver or kidney functions. Your physician may need to reduce your dose or may guide you not to use the medicine, 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 an ECG test (tracing of the heart's electrical activity) shows an abnormal result called QT prolongation or if you take medicines known to be capable of causing this condition, such as:
    - Medicines used to treat arrhythmia, such as: Quinidine, Sotalol, Procainamide, Ibutilide, Flecainide, Dofetilide, Amiodarone.
    - Medicines for treatment of allergic rhinitis.
    - Anti-psychotic medicines (medicines for treatment of mental illnesses) such as Thioridazine, Mesoridazine, Haloperidol and Chlorpromazine.
    - Anti-infective medicines such as Pentamidine, Moxifloxacin, Erythromycin, Clarithromycin.

**Mirabegron 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 Mirabegron**

**If you are currently taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or the pharmacist. The physician or the pharmacist should especially be informed if you take:**

- Thioridazine –medicine for the treatment of mental illnesses - the physician may need to adjust the dose.
- Propafenone, Flecainide - medicines for the treatment of arrhythmia - the physician may need to adjust the dose of these medicines.
- Imipramine or Desipramine - antidepressant medicines - the physician may need to adjust the dose of these medicines.
- Digoxin - medicine for the treatment of heart failure or arrhythmia - your physician will examine the medicine levels in your blood. If the medicine level in your blood will be out of the required range, the physician may adjust the dose of this medicine.
- Dabigatran etexilate - a medicine which is used to reduce the risk of brain or body vessel obstruction by blood clot formation in adult patients with an abnormal heart beat (atrial fibrillation) and additional risk factors. This medicine may require dose adjustment by your doctor.

**Use of the medicine and food:** The medicine may be taken with or without food**.**

**Pregnancy and breastfeeding:** Do not use the medicine if you are pregnant, think you may be pregnant or planning to have a baby.
If you are breastfeeding, you should consult the physician or the pharmacist before using the medicine. It is likely that the medicine passes into your breastmilk and thus the physician and you should decide whether to use the medicine or breastfeed. Do not breastfeed while using the medicine.

**Driving and using machinery:** There is no information indicating that this medicine has an impact on the ability to drive or use machines.

## 3. How should you use the medicine?

Always use according to the physician's instructions.

You should check with the physician or the pharmacist if you are unsure.
The dosage and treatment regimen will be determined only by the physician. Normally, the usual dose is one tablet of 50mg once daily. If you have a problem with liver or kidney functions, the physician may need to decrease the dose to one tablet of 25mg once daily.

**Do not exceed the recommended dose.**

**directions for use:**

- The medicine should be swallowed as a whole with water.
- Do not crush, split or chew the tablet, as it is intended for prolonged release.

**If you have taken an overdose by mistake, or if a child has swallowed some of the medicine by mistake**, refer immediately to a physician or the hospital's Emergency Room and bring with you the package of the medicine. Symptoms of overdose may be, among others, forceful heartbeats, increase in heart rate or increase of blood pressure.

**If you forgot to take this medicine at the designated time**, you should take a dose immediately when you remembered it. If you remembered to take the dose less than 6 hours before the next scheduled dose, the missed dose should be skipped and you should continue taking the medicine at the usual time. You should never take two doses at once!
If you miss several doses, tell the physician and act according to his advice.

You should adhere to the treatment as recommended by the physician.
Even if there is an improvement in your health condition, you should not stop the treatment with the medicine without consulting the physician.

**If you stop taking the medicine:** Do not stop the use of Betmiga early if you do not notice an immediate effect. It is possible that some time may pass before the medicine impacts the bladder condition. You should continue taking the tablets and should not stop using of the medicine when the bladder's condition improves. Discontinuation of treatment may cause a return of the overactive bladder symptoms.

Do not take medicines in the dark! Check the label and dose each time you take a medicine.
Wear eyeglasses if you need them.
If you have further questions about the medicine's use, consult the physician or pharmacist.

## 4. Side effects.

Like with any medicine, the use of Betmiga might cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not suffer any of them.

**Discontinue the use and contact the physician at once**
In case of irregular heart beat (atrial fibrillation) the use of the medicine should be discontinued immediately and treatment must be sought. This phenomenon is not common (may appear in 1-10 users out of 1,000).

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

other side effects:

**Common side effects (may affect 1-10 users out of 100):**

- Increased heart rate (tachycardia)
- Urinary tract infections
- Nausea
- Constipation
- Headache

- Diarrhoea
- Dizziness

**Uncommon side effects (may affect 1-10 users out of 1,000):**

- Bladder infections (cystitis)
- Pulsation, heart pounding (palpitations)
- Vaginal infection
- Dyspepsia (indigestion)
- infection of the stomach (gastritis)
- Joints swelling
- Itching in the vulva or vagina
- Increased blood pressure
- Increase of liver enzymes (ALT, AST, GGT)
- itching, rash or hives.

**Rare side effects (may affect 1-10 users out of 10,000):**

- Swelling of the eyelids
- Swelling of the lips
- Swelling of the deep layers of the skin as a result of fluid accumulation, which may affect any part of the body, including the face, tongue or throat and may cause breathing difficulties (angioedema).
- Small purple spots on the skin (purpura)
- Inflammation of the small blood vessels in the skin (leukocytoclastic vasculitis)
- Inability to completely empty the bladder (urinary retention)

**Very Rare (may affect up to 1 in 10,000 people)**

- Drastic and severe increase in blood pressure (Hypertensive crisis)

**Not known (frequency cannot be estimated from the available data)**

- Insomnia
- Confusion

Betmiga might increase the chances of you not being able to empty the bladder if you suffer from an bladder outlet obstruction or if you take other medicines for the treatment of an overactive bladder. The physician should be updated immediately if you cannot empty the bladder.
If a side effect appears, or if one of the side effects exacerbates, or when you have a side effect not mentioned in this leaflet, you should consult the physician.

Any suspected adverse events should be reported to the Ministry of Health using an online form in the Ministry of health home page www.health.gov.il or by using the link: https://sideeffects.health.gov.il/

## 5. How to store the medicine?

Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach of children and/or infants, and thus poisoning will be avoided.

Do not cause vomiting unless explicitly instructed by the physician.

Do not use the medicine after its expiry date (exp. date) which appears on the package. The expiry date refers to the last day of that month.

Store below 25°C, in its original packaging.

## 6. Additional information.

In addition to the active substances, the medicine also contains:

Tablet core:

Magnesium stearat ,Butylhydroxytoluene ,Hydroxypropylcellulose, Macrogols

Tablet's coating:

Hypromellose, Macrogol, Iron oxide yellow (E172),

Iron oxide red (E172) - present only in Betmiga 25mg

**What does the medicine look like and what are the contents of the package:**

Betmiga 25mg - prolonged release coated tablets - oval, brown tablets, debossed with "325" and the company's logo on the same side.

Betmiga 50mg - prolonged release coated tablets - oval, yellow- tablets, debossed with "355" and the company's logo on the same side.

The tablets are in a blister packs, and the blisters are in a cardboard package.

**Name and address of the registration owner:**

Astellas Pharma International B.V., Rosh Ha'Ayin, Israel

**Name and address of Manufacturer:**
Astellas Pharma Europe B.V.

Sylviusweg 62, 2333 BE Leiden, The Netherlands

Approved in: **08.2016**
Revised in: **08.2024** according to MoH guidelines

**Registration number of the medicine in the national Drug Registry of the Ministry of Health:**
Betmiga 25mg - 153-46-34104
Betmiga 50mg - 153-47-34113