PACKAGE LEAFLET

Package leaflet: Information for the user

Mirabegron Teva 25 mg prolonged-release tablets
mirabegron

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Mirabegron Teva is and what it is used for
2. What you need to know before you take Mirabegron Teva
3. How to take Mirabegron Teva
4. Possible side effects
5. How to store Mirabegron Teva
6. Contents of the pack and other information

1. What Mirabegron Teva is and what it is used for

Mirabegron Teva 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 and reduces neurogenic detrusor overactivity.

Mirabegron Teva is used to:
- treat the symptoms of a condition called overactive bladder in adults.
  These symptoms include: 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 to empty your bladder (called urgency incontinence).
- treat a condition called neurogenic detrusor overactivity in children aged 3 to less than 18 years. Neurogenic detrusor overactivity is a condition in which involuntary bladder contractions occur due to a condition that you are born with or injury to the nerves, which control the bladder. If left untreated, neurogenic detrusor overactivity may lead to damage to your bladder and/or kidneys. Mirabegron Teva is used to increase the amount of urine your bladder can hold and reduce urine leakage.

2. What you need to know before you take Mirabegron Teva

Do not take Mirabegron Teva
- if you are allergic to mirabegron or any of the other ingredients of this medicine (listed in section 6);
- if you have very high uncontrolled blood pressure.

Warnings and precautions
Talk to your doctor or pharmacist before taking Mirabegron Teva
- 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 or neurogenic detrusor overactivity 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 Mirabegron Teva, 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 known as QT prolongation or you are taking any medicine known to cause this 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.

Mirabegron Teva 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 this medicine.

Children and adolescents
Do not give this medicine to children and adolescents under 18 years of age for the treatment of overactive bladder because the safety and efficacy of Mirabegron Teva in this population has not been established.

Mirabegron Teva is not to be used in children under 3 years of age for the treatment of neurogenic detrusor overactivity.

Other medicines and Mirabegron Teva
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Mirabegron Teva may affect the way other medicines work, and other medicines may affect how this medicine works.
- Tell your doctor if you use thioridazine (a medicine for mental illness), propafenone or flecainide (medicines for abnormal heart rhythm), imipramine or desipramine (medicines used for depression). These specific medicines may require dose adjustment by your doctor.
- Tell your doctor if you use digoxin (a medicine for heart failure or abnormal heart rhythm). Blood levels of this medicine are measured by your doctor. If the blood level is out of range, your doctor may adjust the dose of digoxin.
- Tell your doctor if you use dabigatran etexilate (a medicine which is used to reduce the risk of brain or body vessel obstruction by blood clot formation in patients with an abnormal heart beat (atrial fibrillation) and additional risk factors). This medicine may require dose adjustment by your doctor.

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby, you must not take Mirabegron Teva.

If you are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine. It is likely that this medicine passes into your breast milk. You and your doctor should decide if you should take Mirabegron Teva or breast-feed. You should not do both.

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

3. How to take Mirabegron Teva

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Use in adults with overactive bladder
The recommended dose is one 50 mg tablet by mouth once daily. If you have kidney or liver problems, your doctor may need to reduce your dose to one 25 mg tablet by mouth once daily. You must take this medicine with liquids and swallow the tablet whole. Do not crush or chew the tablet. Mirabegron Teva can be taken with or without food.

Use in children and adolescents (age 3 to less than 18 years) with neurogenic detrusor overactivity
Take this medicine by mouth once daily. You must take this medicine with liquids and swallow the tablet whole. Do not crush or chew the tablet. Mirabegron Teva must be taken with food. Your doctor will tell you which dose you/your child should take. Your doctor will calculate the correct dose for a patient depending on his or her body weight. You should carefully follow their instructions.

If you take more Mirabegron Teva 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.

If you forget to take Mirabegron Teva
If you forget to take your medicine, take the missed dose as soon as you remember. If it is less than 12 hours before your next scheduled dose, skip the dose and continue to take your medicine 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 Mirabegron Teva
Do not stop treatment with Mirabegron Teva 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 or neurogenic detrusor overactivity.

Do not stop taking Mirabegron Teva without talking to your doctor first, as your symptoms of overactive bladder or neurogenic detrusor overactivity may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most serious side effects may include irregular heart beat (atrial fibrillation). This is an uncommon side effect (may affect up to 1 in 100 people), but **if this side effect occurs, immediately stop taking the medicine 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.

Other side effects include:

Common (may affect up to 1 in 10 people)
- Infection of the structures that carry urine (urinary tract infections)
- Headache
- Dizziness
- Increased heart rate (tachycardia)
- Feeling sick (nausea)
- Constipation
- Diarrhoea

Uncommon (may affect up to 1 in 100 people)
- Vaginal infection
- Bladder infection (cystitis)
- Feeling your heartbeat (palpitations)
- Heart rhythm problems (atrial fibrillation)
- Indigestion (dyspepsia)
- Infection of the stomach (gastritis)
- Itching, rash or hives (urticaria, rash, rash macular, rash papular, pruritus)
- Swelling of the joints
- Itching of the vulva or vagina (vulvovaginal pruritus)
- Increased blood pressure
- Increase in liver enzymes (GGT, AST and ALT)

Rare (may affect up to 1 in 1 000 people)
- Swelling of the eyelid (eyelid oedema)
- Swelling of the lip (lip oedema)
- Inflammation of small blood vessels mainly affecting the skin (leukocytoclastic vasculitis)
- Small purple spots on the skin (purpura)
- 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)
- Inability to completely empty the bladder (urinary retention)

Very rare (may affect up to 1 in 10 000 people)
- Severely high blood pressure (hypertensive crisis)

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

Mirabegron Teva may increase your chances of not being able to empty your bladder if you have bladder outlet obstruction or if you are taking other medicines to treat overactive bladder. Tell your doctor right away if you are unable to empty your bladder.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mirabegron Teva

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Mirabegron Teva contains

- The active substance is mirabegron. Each tablet contains 25 mg of mirabegron.
- The other ingredients are:
  Tablet core: high-molecular-mass macrogols 2 000 000, microcrystalline cellulose, hypromellose 2 208, hydroxypropylcellulose, butylhydroxytoluene, magnesium stearate, colloidal anhydrous silica,
  Film-coating: poly(vinyl alcohol), titanium dioxide, macrogol 3 350, talc

What Mirabegron Teva looks like and contents of the pack
Mirabegron Teva 25 mg prolonged-release tablets are white or almost white, 6 x 13 mm oblong, biconvex film-coated tablets debossed with “l” on one side and plain on the other side.

[For IS/H/0747/001/DC]
Mirabegron Teva is available in blisters in cartons containing 10, 30, 50, 90, 100 tablets.

Not all pack sizes may be marketed.

[For IS/H/0748/001/DC]
Mirabegron Teva is available in blisters in cartons containing 30 tablets.

Marketing Authorisation Holder
TEVA GmbH
Graf-Arco-Straße 3
Ulm 89079
Germany

Manufacturer
Pharmadox Healthcare Limited,
Kw20a Kordin Industrial Park
Paola
PLA 3000
Malta

Adalvo Limited,
Malta Life Sciences Park, Building 1, Level 4
Sir Temi Zammit Building
San Gwann
SGN 3000
Malta

This medicine is authorised in the Member States of the European Economic Area under the following names:

Iceland	Mirabegron Teva
Austria	Mirabegron ratiopharm 25 mg Retardtabletten
Belgium	Mirabegron Teva 25 mg tabletten met verlengde afgifte
Germany	Mirabegron-ratiopharm 25 mg Retardtabletten

Denmark	Mirabegron Teva
Finland	Mirabegron ratiopharm 25 mg depottabletti
Ireland	Mirabegron Teva 25 mg prolonged-release tablets
Norway	Mirabegron Teva
Portugal	Mirabegrom Teva
Sweden	Mirabegron Teva

This leaflet was last revised in 09/2026