Package leaflet: Information for the patient

Mirabegron Teva 50 mg, tabletten met verlengde afgifte
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 [Product Name] is and what it is used for

[Product Name] 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.

[Product Name] is used to treat the symptoms of an overactive bladder in adults 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 to empty your bladder (called urgency incontinence)

2. What you need to know before you take [Product Name]

Do not take [Product Name]
- 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 [Product Name]:
- 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 [Product Name], 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 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 the age of 18 years because the safety and efficacy of mirabegron in this age group has not been established.

Other medicines and [Product Name]
Tell your doctor or pharmacist if you are taking, have recently used or might use any other medicines.

[Product Name] 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 adult 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 should not take [Product Name].

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 [Product Name] or breastfeed. 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 [Product Name]

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

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 25 mg by mouth once daily. In case your doctor recommends you to take 25 mg mirabegron, you should use other medicinal products containing 25 mg mirabegron available on the market. Do not split the 50 mg tablet as this might impact the way that this medicine works.

You should take this medicine with liquids and swallow the tablet whole. Do not crush or chew the tablet. [Product Name] can be taken with or without food.

If you take more [Product Name] 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 [Product Name]
If you forget to take your medicine, take the missed dose as soon as you remember. If it is less than 6 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 [Product Name]
Do not stop treatment with [Product Name] 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.

Do not stop taking [Product Name] without talking to your doctor first, as your overactive bladder symptoms 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)
- Increased heart rate (tachycardia)
- Infection of the structures that carry urine (urinary tract infections)
- Nausea
- Constipation
- Headache
- Diarrhoea
- Dizziness

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

Rare (may affect up to 1 in 1 000 people)
- Swelling of the eyelid (eyelid oedema)
- Swelling of the lip (lip oedema)
- 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)
- 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)

Very rare (may affect up to 1 in 10 000 people)
- Hypertensive crisis

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

[Product Name] 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 the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product Name]

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 and 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 [Product Name] contains
- The active substance is mirabegron.
  Each tablet contains 50 mg of mirabegron.
- The other ingredients are:
  Tablet core: macrogol 2 000 000; cellulose, microcrystalline (E460); hypromellose type 2 208, K100 (E464); hydroxypropylcellulose; butylhydroxytoluene; magnesium stearate (E572); silica, colloidal anhydrous
  Film-coating: poly(vinyl alcohol); titanium dioxide (E171); macrogol 3 350; talc (E553b); iron oxide yellow (E172) and iron oxide red (E172)

What [Product Name] looks like and contents of the pack
[Product Name] 50 mg prolonged-release tablets are light yellow approximately 6 × 13 mm oblong, biconvex film coated tablets.

[Product Name] is available in Alu-OPA/Alu/PVC blisters in carton packs.

Pack sizes:
10, 30, 50, 90 or 100 prolonged-release tablets

Not all pack sizes may be available.

Houder van de vergunning voor het in de handel brengen en fabrikant
Houder van de vergunning voor het in de handel brengen
Teva Nederland B.V.
Swensweg 5
2031 GA Haarlem
Nederland

Fabrikant
Pharmadox Healthcare Limited
Kw20a Kordin Industrial Park
PLA 3000 Paola
Malta

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

In het register ingeschreven onder: RVG 132822

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

België	Mirabegron Teva 50 mg tabletten met verlengde afgifte / comprimés à libération prolongées / Retardtabletten
Bulgarije	Mirabegron Teva 50 mg prolonged-release tablets
Denemarken	Mirabegron Teva
Duitsland	Mirabegron-ratiopharm 50 mg Retardtabletten
Finland	Mirabegron ratiopharm 50 mg depottabletti
Ierland	Mirabegron Teva 50 mg Prolonged-release Tablets
IJsland	Mirabegron Teva
Nederland	Mirabegron Teva 50 mg, tabletten met verlengde afgifte
Noorwegen	Mirabegron Teva
Oostenrijk	Mirabegron ratiopharm 50 mg Retardtabletten
Polen	Mirabegron Teva
Slowakije	Mirabegron Teva 50 mg
Spanje	Mirabegrón Teva 50 mg comprimidos de liberación prolongada EFG
Tsjechië	Mirabegron Teva
Zweden	Mirabegron Teva

Deze bijsluiter is voor het laatst goedgekeurd in augustus 2024.

<Latest approved information on this medicine is available by scanning the QR code included in the <package leaflet> <outer carton> with a smartphone/device. The same information is also available on the following URL: [URL to be included] <and the <NCA> website>>

In case that only the URL is mentioned in the PI and not linked via mobile technology:

<Latest approved information on this product is available on the following URL: [URL to be included] <and the <NCA> website>>