

**Patient Information**  
**MYRBETRIQ® (meer-BEH-trick)**  
**(mirabegron)**  
**extended-release tablets**

Read the Patient Information that comes with MYRBETRIQ® before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or treatment.

**What is MYRBETRIQ®?**

MYRBETRIQ® is a prescription medicine for adults used to treat the following symptoms due to a condition called overactive bladder:

- Urge urinary incontinence: a strong need to urinate with leaking or wetting accidents
- Urgency: a strong need to urinate right away
- Frequency: urinating often

It is not known if MYRBETRIQ® is safe and effective in children.

**Who should not use MYRBETRIQ®?**

Do not use MYRBETRIQ® if you have an allergy to mirabegron or any of the ingredients in MYRBETRIQ®. See the end of this leaflet for a complete list of ingredients in MYRBETRIQ®.

**What should I tell my doctor before taking MYRBETRIQ®?**

Before you take MYRBETRIQ®, tell your doctor if you:

- have liver problems
- have kidney problems
- have very high uncontrolled blood pressure
- have trouble emptying your bladder or you have a weak urine stream
- are pregnant or plan to become pregnant. It is not known if MYRBETRIQ® will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if MYRBETRIQ® passes into your breast milk. You and your doctor should decide if you will take MYRBETRIQ® or breastfeed. You should not do both.

**Tell your doctor about all the medicines you take**, including prescription and nonprescription medicines, vitamins, and herbal supplements. MYRBETRIQ® may affect the way other medicines work, and other medicines may affect how MYRBETRIQ® works.

Tell your doctor if you take:

- thioridazine (Mellaril™ or Mellaril-S™)
- flecainide (Tambacor®)
- propafenone (Rythmol®)
- digoxin (Lanoxin®)

### **How should I take MYRBETRIQ®?**

- Take MYRBETRIQ® exactly as your doctor tells you to take it.
- You should take 1 MYRBETRIQ® tablet 1 time a day.
- You should take MYRBETRIQ® with water and swallow the tablet whole.
- Do not crush or chew the tablet.
- You can take MYRBETRIQ® with or without food.
- If you miss a dose of MYRBETRIQ®, begin taking MYRBETRIQ® again the next day. Do not take 2 doses of MYRBETRIQ® the same day.
- If you take too much MYRBETRIQ®, call your doctor or go to the nearest hospital emergency room right away.

### **What are the possible side effects of MYRBETRIQ®?**

MYRBETRIQ® may cause serious side effects including:

- **increased blood pressure.** MYRBETRIQ® 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 MYRBETRIQ®.
- **inability to empty your bladder (urinary retention).** MYRBETRIQ® 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.
- **angioedema.** MYRBETRIQ® may cause an allergic reaction with swelling of the lips, face, tongue, throat with or without difficulty breathing. Stop using MYRBETRIQ® and tell your doctor right away.

The most common side effects of MYRBETRIQ® include:

- increased blood pressure
- common cold symptoms (nasopharyngitis)
- urinary tract infection
- constipation
- diarrhea
- dizziness
- headache

Tell your doctor if you have any side effect that bothers you or that does not go away or if you have swelling of the face, lips, tongue, or throat, hives, skin rash or itching while taking MYRBETRIQ®.

These are not all the possible side effects of MYRBETRIQ®. For more information, ask your doctor or pharmacist.

**Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.**

### **How should I store MYRBETRIQ®?**

- Store MYRBETRIQ® between 59°F to 86°F (15°C to 30°C). Keep the bottle closed.
- Safely throw away medicine that is out of date or no longer needed.

**Keep MYRBETRIQ® and all medicines out of the reach of children.**

### **General information about the safe and effective use of MYRBETRIQ®**

Medicines are sometimes prescribed for purposes other than those listed in the Patient Information leaflet. Do not use MYRBETRIQ<sup>®</sup> for a condition for which it was not prescribed. Do not give MYRBETRIQ<sup>®</sup> to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about MYRBETRIQ<sup>®</sup>. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about MYRBETRIQ<sup>®</sup> that is written for health professionals.

For more information, go to [www.Myrbetriq.com](http://www.Myrbetriq.com) website or call 1-800-727-7003.

### **What are the ingredients in MYRBETRIQ<sup>®</sup>?**

**Active ingredient:** mirabegron

**Inactive ingredients:** polyethylene oxide, polyethylene glycol, hydroxypropyl cellulose, butylated hydroxytoluene, magnesium stearate, hypromellose, yellow ferric oxide and red ferric oxide (25 mg MYRBETRIQ<sup>®</sup> tablet only).

### **What is 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 of overactive bladder, which are urinary frequency, urinary urgency, and urinary incontinence (leakage).

### **Rx Only**

PRODUCT OF JAPAN OR IRELAND – See bottle label or blister package for origin

Marketed and Distributed by:

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Northbrook, Illinois 60062

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Revised: July 2017

17A004-MIR-PPI