Patient Information
MYRBETRIQ® (meer-BEH-trick)
mirabegron
extended-release tablets
for oral use

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 that can be used alone or with solifenacin succinate 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, when used alone or with solifenacin succinate, is safe and effective in children.

Who should not take MYRBETRIQ?
Do not take 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 about all of your medical conditions, including 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. Talk to your doctor about the best way to feed your baby if you take MYRBETRIQ.

Tell your doctor about all the medicines you take, including prescription and over-the-counter 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 (Tambocor)
- propafenone (Rythmol)
- digoxin (Lanoxin)
- solifenacin succinate (VESIcare®)

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.
- If your doctor prescribes MYRBETRIQ and solifenacin succinate together, you should take 1 MYRBETRIQ tablet and 1 solifenacin tablet at the same time, 1 time a day.
- You should take MYRBETRIQ with water and swallow the tablet whole.
- Do not chew, break, or crush the tablet.
- You can take MYRBETRIQ with or without food.
- You can take MYRBETRIQ and solifenacin succinate together 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:

<table>
<thead>
<tr>
<th>Increased blood pressure</th>
<th>Dizziness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common cold symptoms (nasopharyngitis)</td>
<td>Joint pain</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>Headache</td>
</tr>
<tr>
<td>Flu symptoms</td>
<td>Constipation</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>Sinus (sinus irritation)</td>
</tr>
<tr>
<td>Back pain</td>
<td>Inflammation of the bladder (cystitis)</td>
</tr>
</tbody>
</table>

The most common side effects of MYRBETRIQ, when used with solifenacin succinate, include:

- Dry mouth
- Urinary tract infection
- Constipation
- Fast heartbeat

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.

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 for a condition for which it was not prescribed. Do not give MYRBETRIQ to other people, even if they have the same symptoms you have. It may harm them.

You can ask your doctor or pharmacist for information about MYRBETRIQ that is written for health professionals.

What are the ingredients in MYRBETRIQ?

**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 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).

Marketed and Distributed by:
Astellas Pharma US, Inc.
Northbrook, Illinois 60062

MYRBETRIQ® and VESIcare® are registered trademarks of Astellas Pharma Inc. All other trademarks are the property of their respective owners.

© 2012 – 2018 Astellas Pharma US, Inc.

206813-MRVS-PPI

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