

PART III: CONSUMER INFORMATION**PrMYRBETRIQ®
mirabegron**

This leaflet is part III of a three-part "Product Monograph" published when MYRBETRIQ was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MYRBETRIQ. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

MYRBETRIQ treats the symptoms of an overactive bladder such as:

- suddenly needing to empty your bladder (called urgency)
- having to empty your bladder more than usual (called urinary frequency)
- not being able to control when you empty your bladder (called urgency incontinence)

What it does:

MYRBETRIQ contains mirabegron. It works by relaxing the bladder smooth muscle, thereby reducing the symptoms of an overactive bladder.

When it should not be used:

- you have very high uncontrolled blood pressure
- if you are allergic to mirabegron or any of the ingredients in MYRBETRIQ
- women who are pregnant or breastfeeding

What the medicinal ingredient is:

Mirabegron

What the nonmedicinal ingredients are:

butylated hydroxytoluene, hydroxypropyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, polyethylene oxide, yellow ferric oxide and red ferric oxide (25 mg only).

What dosage forms it comes in:

Extended-release tablets, 25 mg, 50 mg

WARNINGS AND PRECAUTIONS

BEFORE you use MYRBETRIQ talk to your doctor or pharmacist if:

- you have problems emptying your bladder or if you have weak urine stream
- you are pregnant or trying to become pregnant
- you are breastfeeding or planning to breastfeed
- you have severe liver problems
- you have severe kidney problems
- you have an eye problem called Glaucoma
- you have high blood pressure or a history of high blood pressure

- you have any heart disorder, including an irregular heartbeat, an abnormal electrical signal called "prolongation of the QT interval" or a known history of QT interval prolongation
- you have a history of ischemic heart disease or a heart rate that is higher than normal

MYRBETRIQ should not be given to patients under 18 years of age.

INTERACTIONS WITH THIS MEDICATION

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. You may need to change the dosage or stop taking one of the medicines.

MYRBETRIQ may interact with the following medications:

- Propafenone, or Flecainide, drugs used to treat irregular heartbeats
- Digoxin
- Drugs known to increase the heartbeat or elevate blood pressure
- Drugs known to prolong the QT/QTc interval and/or cause torsade de pointes

PROPER USE OF THIS MEDICATION**Usual starting dose:**

25 mg once daily with or without food. The tablet should be swallowed whole with a glass of water. Do not crush or chew the tablet. Based upon your response and tolerability, your doctor may increase your dose to 50 mg once daily. The maximum dose for MYRBETRIQ is 50 mg once daily.

Overdose:

In case of drug overdose, contact your doctor, or a poison control centre, or go to emergency room of the hospital near you immediately, even if there are no symptoms.

Missed Dose:

If you forget to take your medicine, then take your next dose at the normal 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medications, MYRBETRIQ can cause side effects. The possible common side effects are as follows:

- Increased blood pressure
- Cold symptoms (Nasopharyngitis)
- Urinary tract infection
- Constipation
- Diarrhea
- Dizziness
- Headache
- Nausea
- Itching

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Rash / Urticaria (hives)			✓
	Urinary Retention (the inability to empty your bladder)			✓
	Atrial fibrillation (rapid and irregular heart beat)			✓
	Cerebrovascular accident (stroke)			✓
Rare	Angioedema (swelling of the face or tongue, difficulty breathing)			✓

This is not a complete list of side effects. For any unexpected effects while taking MYRBETRIQ, contact your doctor or pharmacist.

HOW TO STORE IT

Keep out of the reach and sight of children. Store at 25°C (77°F) with excursions permitted from 15°C to 30°C (59°F to 86°F).

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage-paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:
<http://www.astellas.ca>
or by contacting the sponsor, Astellas Pharma Canada, Inc., at: 1-888-338-1824

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