

## PART III: CONSUMER INFORMATION

PR RAPAFLO®  
Silodosin Capsules

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

**Please read this leaflet before you start taking RAPAFLO (silodosin). Also, read it each time you renew your prescription, just in case new information has been added.**

### ABOUT THIS MEDICATION

#### What the medication is used for:

Your doctor has prescribed RAPAFLO because you have a medical condition called benign prostatic hyperplasia (BPH). This only occurs in men.

#### What it does:

RAPAFLO relaxes muscles in the prostate, bladder neck and base. This results in improved urine flow, and reduced BPH symptoms.

#### When it should not be used:

Do not use RAPAFLO if you:

- are allergic to silodosin or to any ingredient in RAPAFLO (see **What the nonmedicinal ingredients are**);
- take other alpha<sub>1</sub>-blockers for high blood pressure;
- take antifungal or HIV drugs such as ketoconazole, itraconazole (Sporanox®), ritonavir (Kaletra®, Norvir®);
- have severe liver problem; or
- have severe kidney problem.

#### What the medicinal ingredient is:

Silodosin

#### What the nonmedicinal ingredients are:

D-mannitol, magnesium stearate, pregelatinized starch, and sodium lauryl sulfate. The size #1 and #3 hard gelatin capsules contain gelatin and titanium dioxide. The #1 capsules are printed with edible ink containing FD&C Blue No. 1 Aluminum Lake and yellow iron oxide. The #3 capsules are printed with edible ink containing yellow iron oxide.

#### What dosage forms it comes in:

Hard gelatin capsules.  
8 mg capsules contain 8 mg of silodosin.  
4 mg capsules contain 4 mg of silodosin.

### WARNINGS AND PRECAUTIONS

RAPAFLO may lower blood pressure (postural hypotension), and may make you feel dizzy, especially when getting up from a lying or sitting position particularly if you are taking medications to lower blood pressure or have low blood pressure. In such cases, lie down until the symptoms have completely disappeared. Do not drive or operate machinery until you know how RAPAFLO affects you.

RAPAFLO is not indicated nor recommended for use in women and children.

Prostate cancer and BPH cause many of the same symptoms. Prior to starting RAPAFLO, your doctor will examine you to rule out the presence of prostate cancer.

Tell your doctor or pharmacist, before using the medication, if:

- you suffer liver or kidneys problems;
- you have ever had a reaction to the ingredients of this medication; or
- you have had low blood pressure or signs of low blood pressure [fainting, dizziness] after taking another medicine.

If you will have eye surgery, you must inform your eye surgeon that you are currently using RAPAFLO. Intraoperative Floppy Iris Syndrome (IFIS) has been reported during cataract surgery in some patients who take or have taken alpha<sub>1</sub>-blockers.

### INTERACTIONS WITH THIS MEDICATION

RAPAFLO is broken down by specific enzymes in the liver. It is not known how combined use of drugs, or herbal products that are also broken down by the same enzymes, or grapefruit juice may influence the effectiveness or unwanted side effects of these drugs or herbal medicines.

Before using any prescription, over-the-counter medicines or herbal products, check with your doctor or your pharmacist.

Drugs that interact with RAPAFLO include:

- Alpha<sub>1</sub>-blockers for high blood pressure or prostate problems
- Certain anti-infection drugs such as ketoconazole, clarithromycin, itraconazole (Sporanox®) and ritonavir (Kaletra®, Norvir®)

**PROPER USE OF THIS MEDICATION**

**Usual dose:**

Follow your doctor’s instructions very carefully about how to take RAPAFLO.

The recommended dosage is one capsule (8 mg) daily to be taken right after a meal, at the same time each day.

For those with moderate renal impairment, the recommended dosage is one capsule (4 mg) daily to be taken right after meal, at the same time each day.

If you stop taking RAPAFLO for several days, you must check with your doctor before starting it again.

**Overdose:**

Overdose of silodosin may lead to low blood pressure and change in heart rate.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all prescription drugs, RAPAFLO may cause side effects.

The most common side effect seen with RAPAFLO is an orgasm with reduced or no semen. This side effect is reversible with discontinuation of the product. Other common side effects include dizziness, diarrhea, lightheadedness upon standing or sitting up abruptly, headache, swelling of the throat and nasal passages, and stuffy nose. Cases of itching, hives, shortness of breath, eosinophilic pneumonia (cough, fever, difficulty breathing), dry cough, swelling under the skin, peeling of skin, redness of skin, and swelling of the face have also been reported. If these side effects persist or become bothersome, please check with your physician or pharmacist.

As with other alpha-blockers, RAPAFLO can cause a drop in blood pressure upon changing from a sitting to a standing position, especially when you start treatment. This may lead to fainting, dizziness, or lightheadedness, upon standing or sitting up abruptly. Be careful when driving, operating machinery, or when doing any dangerous activities until you know how RAPAFLO affects you. This is important if you already have a problem with low blood pressure or take medicines to treat high blood pressure. If you begin to feel dizzy or lightheaded, lie down with your legs and feet up. If your symptoms do not improve call your doctor.

If you are undergoing cataract surgery or surgery because of cloudiness in your lens you should inform your ophthalmologist that you are taking RAPAFLO.

**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 |   |
| Common           | Dizziness   | ✓                                   |              |   |
|                  | Headache  | ✓                                   |              |   |
| Uncommon         | Fainting  |                                     | ✓            |   |
|                  | Lightheadedness upon standing or sitting up abruptly  |                                     | ✓            |   |
|                  | Liver disease or liver problems   |                                     | ✓            |   |
|                  | Allergic reactions (swollen tongue, swollen throat)   |                                     |              | ✓   |
|                  | Skin rash   |                                     |              | ✓   |
|                  | Red or purple discoloration of the skin caused by bleeding underneath the skin (known as purpura) | ✓                                   |              |   |
|                  | Fast heart rate (tachycardia)   |                                     | ✓            |   |
| Rare             | Feeling of rapid beating of the heart that may be more forceful (palpitation)                     |                                     | ✓            |   |

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

## HOW TO STORE IT

RAPAFLO capsules should be stored at controlled room temperature (15°C to 30°C). Protect from light and moisture.

Keep RAPAFLO out of reach of children.

### **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](http://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 0701E  
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](http://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 [allergan.ca](http://allergan.ca) or by contacting Allergan Inc. at 1-800-668-6424.

This leaflet was prepared by:  
Allergan Inc.  
Markham, Ontario L6G 0B5

Under Licence From:  
Kissei Pharmaceutical Co., Ltd.  
Nagano  
JAPAN

RAPAFLO® and its design are registered trademarks of Allergan Sales, LLC, used under license by Allergan Inc.

Date of Preparation: March 12, 2018