PART III: CONSUMER INFORMATION

*Sandoz Tamsulosin
tamsulosin hydrochloride
0.4 mg sustained-release capsules

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

Please read this leaflet before you start taking Sandoz Tamsulosin (tamsulosin hydrochloride). Also, read it each time you renew your prescription, just in case new information has been added.

ABOUT THIS MEDICATION

What this medication is used for:
• Sandoz Tamsulosin is for use by men only.
• Your physician has prescribed Sandoz Tamsulosin because you have a medical condition called benign prostatic hyperplasia or BPH. This occurs only in men.

What it does:
Sandoz Tamsulosin acts by relaxing muscles in the prostate and bladder neck at the site of the obstruction, resulting in improved urine flow, and reduced BPH symptoms.

What is BPH? BPH is an enlargement of the prostate gland. After age 50, most men develop enlarged prostates. The prostate is located below the bladder. As the prostate enlarges, it may slowly restrict the flow of urine. This can lead to symptoms such as:
• having a weak urinary system;
• a sensation of not emptying your bladder completely after you finish urinating;
• pushing or straining to begin urination;
• stopping and starting again several times when urinating;
• urinating again less than 2 hours after you finish urinating;
• finding it difficult to postpone urination;
• frequent sleep interruption caused by a need to urinate.

When it should not be used:
You should not use Sandoz Tamsulosin if you are allergic (hypersensitive) to tamsulosin or any of the other ingredients in Sandoz Tamsulosin. Hypersensitivity may present as sudden local swelling of the soft tissues of the body (e.g. the throat or tongue), difficult breathing and/or itching and rash (angioedema).

What the medicinal ingredients are:
Methacrylic acid-ethyl acrylate copolymer (polysorbate 80, sodium lauryl sulfate), microcrystalline cellulose, talc, and triethylcitrate. The capsule shells are composed of: black iron oxide, FD&C Blue No.2, gelatin, red iron oxide, titanium dioxide, yellow iron oxide. Capsule imprinting ink contains: antifoam, black iron oxide, shellac glaze, and soya lectin.

What dosage forms it comes in:
Sustained-Release Capsules

WARNINGS AND PRECAUTIONS

Rarely, fainting can occur during the use of Sandoz Tamsulosin, as with other medicinal products of this type. At the first signs of dizziness or weakness you should sit or lie down until they have disappeared.

Sandoz Tamsulosin should not be used in women or children.

BEFORE you use Sandoz Tamsulosin talk to your doctor or pharmacist:
• if you suffer from severe liver problems;
• if you suffer from fainting due to reduced blood pressure when changing posture (going to sit or stand up);
• if you have kidney problems;
• if you have previously taken Sandoz Tamsulosin and became unwell;
• if you are going to drive, operate machinery or perform hazardous tasks.

You must see your doctor regularly. While taking Sandoz Tamsulosin, you must have regular checkups. Follow your doctor's advice about when to have these checkups.

If you are undergoing eye surgery because of cloudiness of the lens (cataract) please inform your eye specialist that you are using or have used Sandoz Tamsulosin. The specialist can then take appropriate precautions with respect to medication and surgical techniques to be used. Ask your doctor whether or not you should temporarily stop taking this medicine when undergoing eye surgery because of a cloudy lens.

INTERACTIONS WITH THIS MEDICATION

Taking Sandoz Tamsulosin with other medicines from the same class (alpha1-adrenoceptor blockers) may cause an unwanted decrease in blood pressure.

Please tell your doctor or pharmacist if you are taking or have recently taken cimetidine or any other medicines, including medicines obtained without a prescription.

PROPER USE OF THIS MEDICINE

Usual dose:
Follow your doctor’s advice about how to take Sandoz
**Tamsulosin.** You should take one capsule (0.4 mg) approximately one-half hour following the same meal each day.

Do not crush, chew, or open capsules of Sandoz Tamsulosin sustained-release formulation. These capsules are specially formulated to control the delivery of tamsulosin hydrochloride to the blood stream.

Do not share Sandoz Tamsulosin with anyone else; it was prescribed only for you.

If you interrupt your treatment for several days or more, resume treatment after consulting with your physician.

**Overdose:**

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.

Taking too many Sandoz Tamsulosin capsules may lead to an unwanted decrease in blood pressure and an increase in heart rate, with feelings of faintness. Contact your doctor immediately if you have taken too much Sandoz Tamsulosin.

**Missed dose:**

You may take your daily Sandoz Tamsulosin capsule later the same day if you have forgotten to take it as recommended. If you have missed a day, just continue to take your daily capsule as prescribed. Never take a double dose to make up for the forgotten capsule.

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

Like all prescription drugs, Sandoz Tamsulosin may cause side effects. Side effects due to Sandoz Tamsulosin may include:

**Common (1-10%):**

Dizziness, particularly when getting up from a seated or lying position.

Some men may experience dizziness or fainting caused by a decrease in blood pressure after taking Sandoz Tamsulosin. Although these symptoms are unlikely, you should avoid driving or hazardous tasks for 12 hours after the initial dose.

**Uncommon (0.1-1%):**

Headache, palpitations (a feeling of rapid beating of the heart that may be more forceful), reduced blood pressure e.g. when getting up quickly from a seated or lying position sometimes associated with dizziness; runny or blocked nose (rhinitis), diarrhea, feeling sick and vomiting, constipation, weakness (asthenia), rashes, itching and hives (urticaria), abnormal ejaculation. The latter means that semen does not leave the body via the urethra, but instead goes into the bladder. This phenomenon is harmless.

**Rare (0.01-0.1%):**

Rarely, fainting can occur during the use of Sandoz Tamsulosin, as with other medicinal products of this type. At the first signs of dizziness or weakness you should sit or lie down until they have disappeared.

Sudden local swelling of the soft tissues of the body (e.g. the throat or tongue), difficulty breathing and/or itching and rash, often as an allergic reaction (angioedema). If you suspect such symptoms, call your doctor or go to an Emergency Room as soon as possible.

Very rare (<0.01%): Priapism (painful prolonged unwanted erection for which immediate medical treatment is required).

There have been reports that tamsulosin hydrochloride SR capsules and similar medications have caused prolonged, painful erection of the penis, which is unrelieved by sexual intercourse or masturbation. This condition, if untreated, can lead to permanent inability to have an erection. If you suspect such symptoms, call your doctor or go to an Emergency Room as soon as possible.

If you are undergoing eye surgery because of cloudiness of the lens (cataract) and are already taking or have previously taken Sandoz Tamsulosin, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure.

This is not a complete list of side effects. For any unexpected effects while taking Sandoz Tamsulosin, contact your doctor or pharmacist immediately, so that these effects may be properly addressed.

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

<table>
<thead>
<tr>
<th>Symptom / effect</th>
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<tbody>
<tr>
<td>Common Dizziness, particularly when getting up from a seated or lying position</td>
<td>Only if severe</td>
<td>In all cases</td>
</tr>
<tr>
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HOW TO STORE IT

Store between 15ºC and 30ºC.

Keep Sandoz Tamsulosin and all medicines out of the 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
- 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.

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 obtained by contacting the sponsor, Sandoz Canada Inc., at: 1-800-361-3062 or by written request at:
145, Jules-Léger
Boucherville, (QC), Canada
J4B 7K8

or by e-mail at:
medinfo@sandoz.com

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