

PART III: CONSUMER INFORMATION

**Pr Tamsulosin CR
(Tamsulosin Hydrochloride)
Controlled-release Tablets 0.4 mg**

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

Please read this leaflet before you start taking Tamsulosin CR (tamsulosin hydrochloride). 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 Tamsulosin CR because you have lower urinary tract symptoms (LUTS) associated with a medical condition called benign prostatic hyperplasia or BPH.

What it does:

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

BPH is an enlargement of the prostate gland. BPH is the most common cause of lower urinary tract symptoms (LUTS) in elderly males. 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:

- frequent sleep interruption caused by a need to urinate;
- having a weak urinary stream;
- 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.

When it should not be used:

- You should not use Tamsulosin CR if you are allergic (hypersensitive) to tamsulosin or any of the other ingredients in Tamsulosin CR. 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).
- You should not use Tamsulosin CR if you are taking

ketoconazole (an antifungal used to treat fungal skin infections)

What the medicinal ingredient is:

Tamsulosin hydrochloride

What the important non-medicinal ingredients are:

Black iron oxide (E172), butylhydroxytoluene, carmine (E120), colloidal anhydrous silica, hydroxypropylcellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyethylene oxide, quinoline yellow (E104), talc, titanium dioxide.

What dosage forms it comes in:

Controlled-release Tablets. Each tablet contains 0.4 mg tamsulosin hydrochloride.

WARNINGS AND PRECAUTIONS

Rarely, fainting can occur during the use of Tamsulosin CR tablet, 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.

Tamsulosin CR should not be used in women or children.

BEFORE you use Tamsulosin CR 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 are allergic to sulfa drugs;
- if you have kidney problems;
- if you have previously taken Tamsulosin CR and became unwell;
- if you are going to have eye surgery for cataract (cloudiness of the lens of the eye) and/or glaucoma (high pressure inside the eye), ask your doctor if you need to temporarily stop taking this medicine before your surgery. A condition known as Intraoperative Floppy Iris Syndrome (IFIS) has been reported in association with tamsulosin hydrochloride during cataract and glaucoma surgery.

Tamsulosin CR may cause dizziness. Do not drive or operate machinery or perform a hazardous task for 12 hours after taking the initial dose of Tamsulosin CR, or until you know how the medication affects you.

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

INTERACTIONS WITH THIS MEDICATION

Taking Tamsulosin CR 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, ketoconazole, warfarin or any other medicines, including medicines obtained without a prescription.

PROPER USE OF THIS MEDICATION

Usual dose:

Follow your doctor's advice about how to take Tamsulosin CR. You should take one tablet (0.4 mg) once daily at the same time each day with or without food.

Do not crush or chew Tamsulosin CR tablets. These tablets are specially formulated to control the delivery of tamsulosin hydrochloride to the blood stream.

Do not share Tamsulosin CR with anyone else; it is 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.

Missed dose:

You may take your daily Tamsulosin CR tablet 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 tablet as prescribed. Never take a double dose to make up for the forgotten tablet.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

Common (1-10%):

Dizziness (particularly when getting up from a seated or lying position). Abnormal ejaculation (ejaculation disorder). This means that semen does not leave the body via the urethra, but instead goes into the bladder (retrograde ejaculation) or the ejaculation volume is reduced or absent (ejaculation failure).

This phenomenon is harmless.

Uncommon (0.1-1%):

Headache, palpitations (a feeling of rapid beating of the heart that may be more forceful), reduced blood pressure (orthostatic hypotension) 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),

Rare (0.01-0.1%):

Fainting – at the first signs of dizziness or weakness you should sit or lie down until they have disappeared.

Allergic reaction (angioedema) – the symptoms include sudden local swelling of the soft tissues of the body (e.g. the throat or tongue), difficulty breathing and/or itching and rash.

Very rare (<0.01%):

Priapism (painful prolonged unwanted 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. Stevens-Johnson syndrome (a life-threatening skin disorder which can cause: rash, sores in the mouth, and sores on the body).

Not Known (frequency cannot be estimated from the available data)

Blurred vision or impaired vision, nose bleeds (epistaxis), serious skin rashes (erythema multiform, dermatitis exfoliative), dry mouth.

If you are undergoing eye surgery because of cloudiness of the lens (cataract) or high pressure inside the eye (glaucoma) and are already taking or have previously taken tamsulosin hydrochloride, 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 Tamsulosin CR, 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

| 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, particularly when getting up from a seated or lying position | | ✓ | |
| Uncommon | Palpitations (feeling of rapid beating of the heart that may be more forceful) | | ✓ | |
| | Rashes, itching and hives (urticaria) | | | ✓ |
| | Reduced blood pressure e.g. when getting up quickly from a seated or lying position, sometimes associated with dizziness | | ✓ | |
| Rare | Fainting | | | ✓ |
| | *Sudden local swelling of the soft tissues of the body (e.g. the throat or tongue), difficulty breathing and/or itching and rash (angioedema) | | | ✓ |
| Very rare | *Priapism (painful prolonged unwanted erection) | | | ✓ |

* If you suspect such symptoms, call your doctor or go to an Emergency Room as soon as possible.

HOW TO STORE IT

Store at room temperature (15°C - 30°C).

Keep Tamsulosin CR and all medicines 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
- 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

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting Sivem Pharmaceuticals ULC, at: 1-855-788-3153

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