

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

#### **Pr TAMSULOSIN CR**

#### **Tamsulosin Hydrochloride Controlled-Release Tablets**

Read this carefully before you start taking **TAMSULOSIN CR** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TAMSULOSIN CR**.

#### **What is TAMSULOSIN CR used for?**

TAMSULOSIN CR is used to treat the urinary tract symptoms associated with a medical condition called benign prostatic hyperplasia (BPH).

#### **How does TAMSULOSIN CR work?**

TAMSULOSIN CR works by relaxing muscles in the prostate and bladder neck at the site of blockage, 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 older 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 delay urination.

#### **What are the ingredients in TAMSULOSIN CR?**

Medicinal ingredient: Tamsulosin hydrochloride

Non-medicinal ingredients: 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.

**TAMSULOSIN CR comes in the following dosage forms:**

Controlled-release tablets containing 0.4 mg tamsulosin hydrochloride.

**Do not use TAMSULOSIN CR if:**

- you are allergic to tamsulosin or any of the other ingredients in TAMSULOSIN CR or any part of the container.
- you are taking ketoconazole (an antifungal used to treat fungal skin infections).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TAMSULOSIN CR. Talk about any health conditions or problems you may have, including if you:**

- have severe liver problems;
- have fainted due to low blood pressure when going to sit or stand up;
- are allergic to medicines used to treat infections called “sulfonamides” or “sulfa drugs”;
- have kidney problems;
- have previously taken TAMSULOSIN CR and became unwell;
- are going to have eye surgery for cataracts (cloudiness of the lens of the eye) and/or glaucoma (high pressure inside the eye).

**Other warnings you should know about:**

- **Driving and Using Machines:**
  - TAMSULOSIN CR may cause dizziness. Do NOT drive, use machines or perform hazardous tasks for 12 hours after taking TAMSULOSIN CR, or until you know how it affects you.
- **Fainting:**
  - TAMSULOSIN CR may cause you to faint. If you feel dizzy or weak, you should sit or lie down until you feel better.
- **Check-ups and testing:**
  - **You must see your healthcare professional regularly.** While taking TAMSULOSIN CR, you must have regular checkups. Follow your healthcare professional’s advice about when to have these checkups.
- **TAMSULOSIN CR should not be used in women or children.**
- **Surgery:**
  - Tell the healthcare professional you are seeing for the surgery that you are taking this medicine.
  - If you are going to have eye surgery because of cataracts (cloudiness of the lens of the eye) or glaucoma (high pressure inside the eye) and are already taking or have previously taken TAMSULOSIN CR, tell your healthcare professional.

- The pupil may dilate poorly, and the iris (the coloured circular part of the eye) may become floppy during the surgery. This condition is known as “Intraoperative Floppy Iris Syndrome (IFIS)”.
    - This condition has been seen in patients using TAMSULOSIN CR and have surgery for cataracts or glaucoma.
  - Ask your healthcare professional if you need to stop taking this medicine for a period of time before your surgery.
- **Fertility – information for men:**
  - Taking TAMSULOSIN CR may lead to a condition called “ejaculation disorder.” This is when you have an abnormal ejaculation where the semen does not leave the body through the urethra but instead goes into your bladder (retrograde ejaculation).
    - It is also possible for less semen or no semen to be released at all (ejaculation failure).
    - Talk to your healthcare professional if you experience this condition.
  - You may also experience a condition called “Priapism.” This is when you experience a painful and prolonged unwanted erection of the penis (that will not go away through sexual intercourse or masturbation).
    - If not addressed, this condition can lead to the permanent loss of the ability to have an erection (erectile dysfunction or impotence).
    - If you experience this condition, stop taking the drug and get immediate medical help.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.**

**The following may interact with TAMSULOSIN CR:**

- medicines used to lower blood pressure
  - Taking TAMSULOSIN CR with other medicines from the same class (alpha<sub>1</sub>-adrenoceptor blockers like doxazosin, prazosin, and terazosin) may cause an unwanted decrease in blood pressure.
- medicines used to treat erectile dysfunction called “PDE5 inhibitors” like sildenafil and tadalafil.
- ketoconazole (used to treat fungal infections on the skin).
- cimetidine (used to treat heartburn and stomach ulcers).
- warfarin (used to prevent blood clots).

**How to take TAMSULOSIN CR:**

- Take TAMSULOSIN CR exactly as your healthcare professional has told you.
- Swallow TAMSULOSIN CR tablets whole. Do NOT crush or chew TAMSULOSIN CR tablets.

- This medicine has been prescribed specifically for you. Do NOT give your TAMSULOSIN CR to anyone else. It may harm them, even if their symptoms seem to be similar to yours.
- If you stop your medicine for several days or more, talk to your healthcare professional before taking TAMSULOSIN CR again.
- TAMSULOSIN CR can be taken with or without food.

**Usual dose:**

You should take one tablet (0.4 mg) once a day at the same time each day.

**Overdose:**

If you think you, or a person you are caring for, have taken too much TAMSULOSIN CR, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

- If you miss a dose of TAMSULOSIN CR at your usual time, you may take the missed dose later in the same day.
- If you miss a dose for a day, skip the missed dose. Take your next dose at the usual time.
- Do NOT take two doses to make up for a missed dose.

**What are possible side effects from using TAMSULOSIN CR?**

These are not all the possible side effects you may have when taking TAMSULOSIN CR. If you experience any side effects not listed here, tell your healthcare professional.

- abnormal ejaculation
- headache
- runny or blocked nose (rhinitis)
- diarrhea
- vomiting
- feeling sick (nausea)
- constipation
- weakness (asthenia)
- blurred or impaired vision
- nose bleeds (epistaxis)
- serious skin rashes (erythema multiform, dermatitis exfoliative)
- dry mouth
- skin sensitivity to light
- chest discomfort

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
<b>Dizziness:</b> particularly when getting up from a seated or lying position		✓	
<b>UNCOMMON</b>			
<b>Palpitations (feeling of rapid beating of the heart that may be more forceful)</b>		✓	
<b>Urticaria (Rashes, itching and hives)</b>			✓
<b>Orthostatic Hypotension (Reduced blood pressure):</b> when getting up quickly from a seated or lying position, sometimes associated with dizziness		✓	
<b>RARE</b>			
<b>Fainting</b>			✓
<b>Allergic Reaction (Hypersensitivity):</b> Sudden local swelling of the soft tissues of the body (e.g., the throat or tongue), difficulty breathing and/or itching and rash (angioedema)			✓
<b>VERY RARE</b>			
<b>Priapism (painful prolonged unwanted erection)</b>			✓
<b>Stevens-Johnson syndrome (SJS) (severe skin rash):</b> redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or swollen glands			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

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

Keep out of reach and sight of children.

### **If you want more information about TAMSULOSIN CR:**

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer's website [www.sivem.ca](http://www.sivem.ca), or by calling 1-855-788-3153.

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