

PART III: CONSUMER INFORMATION**HYTRIN[®]
terazosin hydrochloride tablets**

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

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

HYTRIN[®] is used to treat:

- § Hypertension (high blood pressure)
- § Benign prostatic hyperplasia (enlargement of the prostate gland)

HYTRIN[®] is for symptomatic benign prostatic hyperplasia (BPH) and not for prostate cancer. It is possible for men to have both BPH and prostate cancer at the same time. HYTRIN[®] is not a treatment for prostate cancer.

Doctors usually recommend that men be checked for prostate cancer once a year when they turn 50 (or 40 if a family member has had prostate cancer). These checks, including Prostate Specific Antigen (PSA), should continue while you are taking HYTRIN[®].

What it does:

HYTRIN[®] works by relaxing blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

HYTRIN[®] also blocks smooth muscle receptors of the bladder neck and the prostate called alpha-1 adrenoceptors. This blockade causes the smooth muscles of the bladder neck and prostate to relax and decreases muscle tone. This can lead to a rapid improvement in urine flow and symptoms within a 2 week period.

When it should not be used:

HYTRIN[®] should not be used if you are allergic to any component of HYTRIN[®], including active ingredient and non-active ingredients.

What the medicinal ingredient is:

terazosin hydrochloride

What the non-medicinal ingredients are:

HYTRIN[®] 1 mg tablets also contain corn starch, lactose monohydrate, magnesium stearate, povidone and talc.

HYTRIN[®] 2 mg tablets also contain corn starch, FD&C yellow No. 6, lactose monohydrate, magnesium stearate, povidone and talc.

HYTRIN[®] 5 mg tablets also contain corn starch, iron oxide, lactose monohydrate, magnesium stearate, povidone and talc.

HYTRIN[®] 10 mg tablets also contain corn starch, FD&C blue No. 2, lactose monohydrate, magnesium stearate, pregelatinized starch and talc.

What dosage forms it comes in:

HYTRIN[®] is available as a tablet in the following strengths: 1 mg, 2 mg, 5 mg and 10 mg.

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions**

- § **HYTRIN[®] should not be used if you have been diagnosed with micturition syncope (fainting shortly after or during urination).**

BEFORE you use HYTRIN[®] talk to your doctor or pharmacist if:

- § you have low blood pressure;
- § you are using sildenafil (e.g., Viagra[®]), tadalafil (e.g., Cialis[®]) or vardenafil (Levitra[®]);
- § you have liver problems;
- § you have kidney problems;
- § you have had or will have prostate surgery;
- § you have pancreatic cancer;
- § you are pregnant or nursing.

During initiation of HYTRIN[®] therapy, after your HYTRIN[®] dose has been increased, or after interruption of therapy when treatment with HYTRIN[®] is resumed you should not drive, operate heavy machinery, or do any hazardous task, until you are used to the effects of HYTRIN[®]. In these cases, for 12 hours after taking HYTRIN[®], you should avoid situations where injury could result should fainting occur. If you begin to feel dizzy, sit or lie down until you feel better.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including natural health products, prescription and non-prescription medicines.

In general, you should avoid the use of phosphodiesterase (PDE5) inhibitors such as sildenafil (e.g., Viagra[®]), tadalafil (e.g., Cialis[®]) or vardenafil (Levitra[®]) when taking HYTRIN[®] due to the risks of developing serious hypotension (low blood pressure).

Administration of HYTRIN[®] with verapamil (e.g., Isoptin[®], Tarka[®] or Chronovera[®]) to hypertensive patients may result in low blood pressure and/or a rapid heart beat.

Do not take these drugs with HYTRIN[®] without your doctor's advice.

PROPER USE OF THIS MEDICATION

Usual dose:

Follow your doctor's instructions very carefully about how to take HYTRIN[®]. The starting dose is 1 mg at bedtime. The 1 mg dose should be maintained during the first week of treatment, and should be taken every day as prescribed by your doctor. Your doctor will then gradually increase the strength of your prescription to 2 mg, 5 mg, or 10 mg depending on how well you respond. The maximum recommended daily dose is 20 mg per day.

You should see an effect on your symptoms in 2 to 4 weeks. While taking HYTRIN[®], you should have regular check-ups to evaluate your progress regarding your BPH and to monitor your blood pressure.

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.

If you or someone you know accidentally takes more than the stated dose, tell your doctor or hospital how much was taken and show them the tablets. Treat even small overdoses seriously.

Missed Dose:

If you forget to take a dose, take another as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed dose at all.

Never double-up on a missed dose.

Talk to your doctor if you have not taken HYTRIN[®] for a few days. You may have to restart at the 1 mg dose. Be cautious about possible dizziness.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its needed effects, a medicine may cause some unwanted effects. These are referred to as "side effects". Although not all of these side effects may occur, if they do occur they may need medical attention.

HYTRIN[®] can cause a sudden drop in blood pressure after the very first dose. You may feel dizzy, faint, or "light-headed", particularly after you get up from bed or from a chair. This is more likely to occur after you have taken the first dose, but can occur at any time while you are taking the drug. It can also occur if you stop taking the drug and then restart treatment.

Because of this effect, your doctor may have told you to take HYTRIN[®] at bedtime. If you take HYTRIN[®] at bedtime but need to get up from bed to go to the bathroom, get up slowly and cautiously until you are sure how the medicine affects you. It is also important to get up slowly from a chair or bed at anytime until you learn how you react to HYTRIN[®].

Other side effects with HYTRIN[®] include back pain, constipation, diarrhea, drowsiness or sleepiness, dry mouth, flatulence, headache, impotence, indigestion, libido decreased, nasal congestion, nausea, urinary frequency, urinary incontinence primarily reported in postmenopausal women, weakness or weight gain.

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 seek immediate emergency medical attention
	Only if severe	In all cases	
Abnormal, irregular or rapid heartbeat (palpitation)			√

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 seek immediate emergency medical attention
	Only if severe	In all cases	
Allergic reaction Swollen mouth, lips, tongue, eyes, extremities, throat or difficulty swallowing or breathing (signs of angioedema). Intestinal angioedema may also occur and is characterized by abdominal pain (with or without nausea or vomiting). If you notice swelling or feel pain in these areas, inform your doctor immediately. You should also inform your doctor if you have unexplained fever, rash or itching.			√
Anxiety			√
Blurred or hazy vision			√
Chest pain			√
Decreased blood pressure or low blood pressure			√
Depression	√		
Difficulty breathing or shortness of breath			√
Drowsiness or sleepiness			√
Fainting			√
Joint inflammation or joint pain	√		
Permanent erection			√
“Puffiness” of the feet or hands, swelling	√		
Rash			√
Sweating			√
Unknown bruising or increased bleeding after a cut			√
Urinary tract infection	√		

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 seek immediate emergency medical attention
	Only if severe	In all cases	
Vomiting			√
Weakness			√

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

HOW TO STORE IT

Keep HYTRIN[®] and all other medicines out of reach of children.
 HYTRIN[®] tablets should be stored at 15 to 25°C.
 Do not take your tablets after the expiry date shown on the label.
 It is important to keep the HYTRIN[®] in the original package.

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 on line 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**
 - **Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9**
- **Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <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:

<http://www.abbott.ca>

or by contacting the sponsor, Abbott Laboratories, Limited, Saint-Laurent, Qc H4S 1Z1 at: 1-800-699-9948

This leaflet was prepared by Abbott Laboratories, Limited.

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