PART III: CONSUMER INFORMATION

TOVIAZ™
(fesoterodine fumarate extended-release tablets)

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

ABOUT THIS MEDICATION

What the medication is used for:
The name of this medication is TOVIAZ. It is used for the treatment of the symptoms of overactive bladder which include frequency, urgency, and urge incontinence or any combinations of these symptoms.

What it does:
TOVIAZ works to prevent bladder contractions or spasms. This results in more bladder capacity and less frequency, urgency and involuntary loss of urine.

When it should not be used:
You should not take TOVIAZ if you have:
- urinary retention,
- gastric retention
- eye problem called uncontrolled-narrow angle glaucoma,
- known hypersensitivity to fesoterodine fumarate, toterodine L-tartrate tablets, toterodine L-tartrate extended-release capsules, soya, peanuts, lactose, or any of the other ingredients in TOVIAZ.

What the medicinal ingredient is:
Fesoterodine fumarate.

What the nonmedicinal ingredients are:
Glyceryl behenate, hypromellose, indigo carmine aluminum lake, lactose monohydrate, soya lecithin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide, and xylitol.

What dosage forms it comes in:
TOVIAZ 4 mg extended-release tablets (light blue with FS engraved)
TOVIAZ 8 mg extended-release tablets (blue with FT engraved)

WARNINGS AND PRECAUTIONS

BEFORE you use TOVIAZ talk to your doctor or pharmacist if:
- you are pregnant, or trying to become pregnant
- you are breastfeeding your child
- you have myasthenia gravis (a chronic autoimmune neuromuscular disease which causes muscle weakness)
- you have stomach problems affecting passage and digestion of food
- you have or have had abnormal increases in heart rate or ischemic heart disease (e.g. angina)
- you have severe liver problems
- you have severe kidney problems
- you have problems emptying your bladder or if you have weak urine stream
- you are receiving treatment for an eye problem called narrow-angle glaucoma
- you have a rare hereditary problem of galactose intolerance or the Lapp lactase deficiency. TOVIAZ extended-release tablets contain lactose.
- you have a family history of soya intolerance or if you are allergic to soya or peanuts. TOVIAZ extended-release tablets contain soya lecithin.

TOVIAZ can cause angioedema (swelling of face or tongue, difficulty breathing) and anaphylactic reactions (hives, difficulty breathing, abdominal cramps, rapid heartbeat and feeling faint). If you experience any of these symptoms, stop taking TOVIAZ and see your doctor immediately.

TOVIAZ should not be given to patients under 18 years of age.

Do not drive a car or operate any machinery until you know how TOVIAZ affects you.

INTERACTIONS WITH THIS MEDICATION

The following list includes some, but not all, of the drugs that may increase the risk of side effects while receiving TOVIAZ. You should check with your doctor or pharmacist before taking any other medication with TOVIAZ.

Drugs that may interact with TOVIAZ include:
- other drugs that possess antimuscarinic/anticholinergic properties (drugs that cause blurred vision, constipation, dry mouth, etc.)
- antifungals (drugs to treat fungal infections, such as, fluconazole, ketoconazole, miconazole or itraconazole)
- antibiotics (ie. erythromycin, clarithromycin)
- vinblastine (a drug to treat some types of cancer)
- antidepressants (mood disorder drugs)
- antipsychotics (drugs to stabilize thinking and behavior)
- medications bought without a prescription or natural health product.
PROPER USE OF THIS MEDICATION

REMEMBER: This medication is for YOU. Never give it to others. It may harm them even if their symptoms are the same as yours.

Usual Dose: The usual starting dose is 4 mg once daily.

Take TOVIAZ with liquid and swallow the tablet whole. You can take TOVIAZ with or without food. Based upon your response and tolerability, your doctor may increase your dose to 8 mg once daily. The maximum dose for TOVIAZ is 8 mg once daily.

Your doctor may give you the lower 4 mg dose of TOVIAZ if you have certain medical conditions, such as severe kidney problems.

Take TOVIAZ as instructed by your doctor. Do not increase, decrease or stop taking TOVIAZ without first talking to your doctor.

Overdose:

If you take too many tablets by accident, call your doctor or pharmacist or a poison control centre or emergency room of the nearest hospital immediately.

Missed Dose:

If you miss taking your tablet, take it as soon as you remember. But if it is almost time for the next dose, skip the missed dose and just take the next dose. Do not take more than one dose at a time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with most drugs, TOVIAZ can cause some side effects.

A very common side effect is dry mouth. Common side effects are constipation, urinary tract infection, dry eyes, upset stomach, dry throat, nausea, upper respiratory tract infection, painful urination, difficulty emptying your bladder, swelling of the extremities, and skin rash. Uncommon side effects are cough, back pain, abdominal pain, and insomnia. Other side effects that have been reported after the drug was marketed include: blurred vision, dizziness, headache, heart palpitations, angioedema, hypersensitivity reactions, hives, and itching.

If you experience dry mouth after taking TOVIAZ, there are a few ways that might help relieve the symptoms:

- Carry a bottle of water and sip a little bit throughout the day or suck on ice chips to provide moisture
- Chew sugarless gum or suck on sugarless hard candy to stimulate saliva production
- Avoid eating salty or spicy foods
- Avoid drinking carbonated, caffeinated and alcoholic beverages
- Avoid using mouth rinses that contain alcohol, as they may dry out the mouth
- Use a humidifier at night
- Ask your pharmacist to recommend an over-the-counter saliva substitute or oral lubricant

Check with your doctor or pharmacist right away if you have any bothersome or unusual effects while taking TOVIAZ.

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

<table>
<thead>
<tr>
<th>Symptom / effect</th>
<th>Talk with your doctor or pharmacist</th>
<th>Stop taking drug and call your doctor or pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncommon Severe Allergic reaction (hives, severe itching, difficulty breathing, abdominal cramps, rapid heartbeat and feeling faint)</td>
<td>Only if severe</td>
<td>√</td>
</tr>
<tr>
<td>Uncommon Acute Urinary Retention (inability to empty your bladder)</td>
<td>In all cases</td>
<td>√</td>
</tr>
<tr>
<td>Uncommon Angioedema (swelling of face or tongue, difficulty breathing)</td>
<td>In all cases</td>
<td>√</td>
</tr>
</tbody>
</table>

This is not a complete list of side effects. For any unexpected effects while taking TOVIAZ, stop taking the drug and contact your doctor or pharmacist.

HOW TO STORE IT

Store at controlled room temperature 25°C with excursions permitted to 15 – 25°C. Protect from moisture.

You should not use your medication after the expiration date printed on the carton and label.

Keep all medications out of the reach of children. This medication could harm them.
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 0701D
    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 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.pfizer.ca

or by contacting the sponsor, Pfizer Canada Inc., at 1-800-463-6001.

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