

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

P^rTOVIAZ[®]

Fesoterodine fumarate extended-release tablets

Read this carefully before you start taking **Toviaz** 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 **Toviaz**.

What is Toviaz used for?

Toviaz is used to treat the symptoms of an overactive bladder in adults. Symptoms of an overactive bladder can include any of the following or combination of the following:

- having to urinate often
- having a strong need to urinate right away
- leaking or wetting accidents due to a strong need to urinate

How does Toviaz work?

Toviaz works by helping to relax the muscles of the bladder. This helps to relieve many of the symptoms of an overactive bladder.

What are the ingredients in Toviaz?

Medicinal ingredients: Fesoterodine fumarate

Non-medicinal ingredients: Glyceryl behenate, hypromellose, indigo carmine aluminum lake, lactose monohydrate, soya lecithin, microcrystalline cellulose, polyethylene glycol/macrogol, polyvinyl alcohol, talc, titanium dioxide, and xylitol.

Toviaz comes in the following dosage forms:

Extended-release tablet:

- 4 mg (light blue with FS engraved)
- 8 mg (blue with FT engraved)

Do not use Toviaz if:

- You are not able to completely empty your bladder (urinary retention).
- You have delayed or slow emptying of the contents in your stomach (gastric retention).
- You have an eye problem called uncontrolled-narrow angle glaucoma which leads to an increase of the pressure inside the eyeball.
- You are allergic to Toviaz or any of its ingredients. For a complete list, see [What are the ingredients in Toviaz?](#)
- You are allergic to lactose, peanuts or soya.
- You are allergic to medicines that contain tolterodine (Detrol[®] or Detrol[®] LA).

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

- Have or have had problems with your heart, such as:
 - abnormal increases in heart rate or rhythm (arrhythmia), or
 - ischemic heart disease, or
 - heart failure
- Take medicines, such as ketoconazole, itraconazole, miconazole, clarithromycin and cimetidine.
- Have stomach problems affecting passage and digestion of food.
- Have severe constipation.
- Have gastrointestinal obstruction disorders (e.g. pyloric stenosis).
- Have problems emptying your bladder or if you have weak urine stream.
- Have liver problems.
- Have a rare hereditary problem of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. Toviaz contains lactose.
- Have myasthenia gravis (a chronic autoimmune neuromuscular disease which causes muscle weakness).
- Are receiving treatment for an eye problem called narrow-angle glaucoma.
- Have kidney problems.
- Are pregnant, or trying to become pregnant.
- Are breastfeeding your child.
- Have a family history of soya intolerance. Toviaz contains soya lecithin.

Other warnings you should know about:

Angioedema and Allergic Reactions: Toviaz can cause:

- angioedema (swelling of face or tongue, difficulty breathing) and
- severe allergic reactions (hives, trouble breathing, abdominal cramps, rapid heartbeat and feeling faint).

If you experience any of these symptoms, stop taking Toviaz and see your doctor **right away**.

Driving and Operating Machinery: Until you know how Toviaz affects you, do not drive or operate a vehicle or potentially dangerous machinery, especially when you first start treatment, or when your dose is changed. Taking Toviaz can cause side effects such as:

- blurred vision,
- dizziness, and
- drowsiness.

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 Toviaz:

- Other drugs similar to Toviaz (antimuscarinic/anticholinergic)
- Drugs to treat fungal infections (such as, fluconazole, ketoconazole, miconazole or itraconazole)
- Drugs to treat ulcers or gastroesophageal reflux disease (GERD) (such as cimetidine)
- Drugs to treat bacterial infections (such as erythromycin, clarithromycin)
- Drugs to treat some types of cancer (such as vinblastine)
- Drugs to treat depression
- Antipsychotics (drugs to stabilize thinking and behavior)

How to take Toviaz:

- Take Toviaz as instructed by your doctor. Do not increase, decrease or stop taking Toviaz without first talking to your doctor.
- Take Toviaz with liquid and swallow the tablet **whole**. Toviaz should not be chewed, divided, or crushed.

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 Adult dose:

- The usual starting dose is 4 mg once daily.
- The maximum daily dose for Toviaz is 8 mg.
- Your doctor may give you the lower 4 mg dose of Toviaz if you have certain medical conditions.
- Based on how you respond to Toviaz upon your response and tolerability, your doctor may increase your dose to 8 mg once daily.

Overdose:

Some of the signs of an overdose could be:

- Dry mouth
- Constipation
- Dry eyes
- Seeing or believing things that are not there (hallucinations)
- Feeling excited
- Convulsions
- Trouble breathing
- Fast heart rate
- Dilated pupils
- Problems emptying your bladder

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

Missed Dose:

If you miss taking your dose, take it as soon as you remember. But if it is almost time for you to take the next dose, skip the missed dose and just take it at your usual time. Do not take two doses at the same time to make up for the dose that you missed.

What are possible side effects from using Toviaz?

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

A very common side effect is dry mouth. 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.

Common side effects are:

- Constipation
- Upset stomach
- Nausea
- Urinary tract infection
- Upper respiratory tract infection
- Dry eyes
- Painful urination
- Difficulty emptying your bladder
- Dry throat
- Swelling of your lower legs and hands
- Skin rash
- Blurred vision
- Dizziness
- Headache

Uncommon side effects are:

- Cough
- Back pain
- Abdominal pain
- Trouble sleeping
- Drowsiness

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.

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

taking Toviaz.

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	
UNCOMMON			
Severe allergic reactions: sudden wheeziness and chest pain or tightness; or swelling of eyelids, face, lips, tongue or throat			√
Urinary retention (inability to pass urine or to empty your bladder): pain			√
Angioedema (swelling of tissue under the skin): difficulty breathing; swollen face, hands and feet, genitals, tongue, throat; Swelling of the digestive tract causing diarrhea, nausea or vomiting			√

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.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 healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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 out of reach and sight of children.

If you want more information about Toviaz:

- 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 <http://www.pfizer.ca>, or by calling 1-800-463-6001.

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