

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

**TOVIAZ® 4 mg
TOVIAZ® 8 mg
Sustained-release tablets**

**Each tablet contains:
fesoterodine fumarate 4 mg, 8 mg**

Inactive ingredients and allergens: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Further information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours. This medicine is generally not indicated in children under the age of 18.

1. WHAT IS THIS MEDICINE INTENDED FOR?

For the treatment of symptoms that may occur in patients with overactive bladder syndrome such as increased urinary frequency and/or urgency and/or urgency incontinence.

Therapeutic group:
Muscarinic receptor antagonist.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient, soya, peanuts or to any of the other ingredients in this medicine, listed in section 6 (see also section 2, 'Important information about some of this medicine's ingredients').
- You are unable to completely empty your bladder (urinary retention).
- Your stomach empties slowly (gastric retention).
- You have an eye disease called narrow angle glaucoma (high pressure in the eye), which is not under control.
- You have excessive weakness of the muscles (myasthenia gravis).
- You have severe ulcerative colitis.
- You have an abnormally large or distended colon (toxic megacolon).
- You have severe liver problems.
- You have kidney problems or moderate to severe liver problems and are taking medicines containing any of the following active ingredients: itraconazole or ketoconazole (used to treat fungal infections), ritonavir, atazanavir, indinavir, saquinavir or nelfinavir (antiviral medicine for treating HIV), clarithromycin or telithromycin (used to treat bacterial infections) and nefazodone (used to treat depression).

Special warnings regarding use of the medicine

Before treatment with TOVIAZ®, tell your doctor if:

- You have difficulties in completely emptying your bladder (for example due to prostate enlargement)
- You previously experienced decreased bowel movements or suffer from severe constipation
- You are being treated for an eye disease called narrow angle glaucoma
- You have serious liver or kidney problems. Your doctor may need to adjust your dose
- You have a disease called autonomic neuropathy, which you notice from symptoms such as changes in your blood pressure or disorders in the bowel or sexual function
- You have a gastrointestinal disease that affects the passage and/or digestion of food
- You have heartburn or belching
- You have an infection of the urinary tract. Your doctor may need to prescribe you antibiotics.

- You have one of the following conditions:
 - an ECG abnormality known as QT prolongation or if you are taking any medicines known to cause this
 - slow heart rate (bradycardia)
 - you suffer from heart disease such as myocardial ischaemia (reduced blood flow to the heart muscle), irregular heartbeat or heart failure.
 - hypokalaemia - a manifestation of abnormally low levels of potassium in your blood.

Children and adolescents

Do not give this medicine to children and adolescents below 18 years of age because it is yet to be established whether it would work for them and whether it would be safe.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- medicines containing the active ingredient amantadine (used to treat Parkinson's disease), medicines used to treat psychiatric diseases, like anti-psychotics and anti-depressives, and medicines used to enhance gastrointestinal motility or to relieve stomach cramps or spasm and to prevent travel sickness (for example medicines containing metoclopramide). Taking these medicines together with TOVIAZ® may lead to worsening or increase in the frequency of side effects such as dry mouth, constipation, difficulty in completely emptying your bladder or drowsiness.
- medicines containing any of the following active ingredients that may increase the break-down of fesoterodine and thus decrease its effect: St. John's Wort (herbal medicinal product), rifampicin (used to treat bacterial infections), carbamazepine, phenytoin and phenobarbital (used, among others, to treat epilepsy).
- medicines containing any of the following active ingredients may increase the blood levels of fesoterodine: itraconazole or ketoconazole (used to treat fungal infections), ritonavir, atazanavir, indinavir, saquinavir or nelfinavir (antiviral medicines for treating HIV), clarithromycin or telithromycin (used to treat bacterial infections), nefazodone (used to treat depression), fluoxetine or paroxetine (used to treat depression or anxiety), bupropion (used for smoking cessation or to treat depression), quinidine (used to treat arrhythmias) and cinacalcet (used to treat hyperparathyroidism).
- medicines containing the active ingredient methadone (used in the treatment of severe pain and abuse problems).

Using this medicine and food

Swallow the tablet whole with a glass of water, with or without food.

Pregnancy and breastfeeding

You should not take the medicine if you are pregnant, as the effects of fesoterodine on pregnancy and the fetus are not known.

It is not known whether the medicine is excreted into human milk; therefore, do not breastfeed during treatment with TOVIAZ®.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Driving and using machines

Use of the medicine can cause blurred vision, dizziness, and sleepiness. If you experience any of these effects, do not drive or use machines.

Important information about some of this medicine's ingredients

TOVIAZ® contains lactose and soya oil

The medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains soya oil. If you are allergic to peanuts or soya, do not use this medicine.

3. HOW TO USE THIS MEDICINE?

Always use this preparation according to your doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by your doctor only.

The recommended starting dose is one 4 mg tablet a day. Based on how you respond to the medicine, your doctor may prescribe you a higher dose, one 8 mg tablet a day.

Do not exceed the recommended dose.

Do not crush/split/chew the tablet! This is because the tablets are sustained-release tablets, and the active ingredient should be released through them gradually and over time.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the scheduled time, take the medicine as soon as you remember, but do not take more than one tablet a day. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor or pharmacist, as your symptoms of overactive bladder may come back again or become worse.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of TOVIAZ[®], may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Stop taking it and contact your doctor immediately if you have a severe allergic reaction that manifests as swelling of the face, mouth or throat. A serious allergic reaction, including angioedema, occurs rarely.

Very common side effects (may affect more than 1 in 10 people):

Dry mouth, this reaction is usually mild or moderate. This may lead to a greater risk of dental caries. Therefore, you should brush your teeth regularly twice daily and see a dentist when in doubt.

Common side effects (may affect up to 1 in 10 people):

Dry eye, constipation, trouble digesting food, straining or pain when emptying the bladder, dizziness, headache, pain in the stomach, diarrhoea, nausea, difficulty sleeping, dry throat.

Uncommon side effects (may affect up to 1 in 100 people):

Urinary tract infection, sleepiness, difficulty tasting, feeling dizzy (vertigo), rash, dry skin, itching, an uncomfortable feeling in the stomach, flatulence, difficulty in completely emptying the bladder (urinary retention), delay in passing urine, extreme tiredness, increased heart rate (tachycardia), palpitations, liver problems, cough, nasal dryness, throat pain, stomach acid reflux, blurred vision.

Rare side effects (may affect up to 1 in 1,000 people):

Urticaria, confusion

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

- **Storage conditions**

Do not store above 25°C. Store in the original package in order to protect from moisture.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:

Lactose monohydrate, microcrystalline cellulose, hypromellose, xylitol, glycerol dibehenate, talc, polyvinyl alcohol, titanium dioxide, polyethylene glycol, soya lecithin, indigo carmine aluminium lake, purified water.

The medicine contains lactose and soya lecithin:

TOVIAZ® 4 mg - 91.125 mg lactose monohydrate.

TOVIAZ® 8 mg - 58.125 mg lactose monohydrate.

What the medicine looks like and contents of the pack:

TOVIAZ® 4 mg – sustained-release tablets are oval, light blue and engraved on one side with the letters "FS".

TOVIAZ® 8 mg – sustained-release tablets are oval, blue and engraved on one side with the letters "FT".

Registration holder and address: Pfizer Pharmaceuticals Israel Ltd., 9 Shenkar St., Herzliya Pituach.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

TOVIAZ® 4 mg – 139-55-31658

TOVIAZ® 8 mg – 139-56-31659

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