Bladder diary

Use this diary to track your bladder habits for a day. Then bring it with you the next time you see your doctor. It may help him or her evaluate if you have overactive bladder (OAB).

date: _____________

<table>
<thead>
<tr>
<th>Time</th>
<th>Drinks/Food What kind? How much?</th>
<th>Trips to Bathroom How many times?</th>
<th>Accidental Leaks How many?</th>
<th>Did you feel a strong urgency to go?</th>
<th>What were you doing at the time?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example</td>
<td>2 cups of coffee</td>
<td>1</td>
<td>0</td>
<td>☑ yes ☐ no</td>
<td>Walking.</td>
</tr>
<tr>
<td>Morning</td>
<td></td>
<td></td>
<td></td>
<td>☐ yes ☐ no</td>
<td></td>
</tr>
<tr>
<td>Afternoon</td>
<td></td>
<td></td>
<td></td>
<td>☐ yes ☐ no</td>
<td></td>
</tr>
<tr>
<td>Evening</td>
<td></td>
<td></td>
<td></td>
<td>☐ yes ☐ no</td>
<td></td>
</tr>
<tr>
<td>Overnight</td>
<td></td>
<td></td>
<td></td>
<td>☐ yes ☐ no</td>
<td></td>
</tr>
<tr>
<td>Daily total:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TOVIAZ® (fesoterodine fumarate) treats the symptoms of overactive bladder (leaks, strong sudden urges to go, going too often).

**Important Safety Information**

If you have certain stomach problems, glaucoma, or cannot empty your bladder, you should not take TOVIAZ.

TOVIAZ may cause allergic reactions that may be serious. If you experience swelling of the face, lips, throat, or tongue, stop taking TOVIAZ and get emergency medical help right away.

Medicines like TOVIAZ can cause blurred vision, dizziness, drowsiness, and decreased sweating. Do not drive, operate machinery, or do unsafe tasks until you know how TOVIAZ affects you. Use caution in hot environments. Drinking alcohol while taking medicines such as TOVIAZ may cause increased drowsiness.

The most common side effects are dry mouth and constipation.

TOVIAZ has benefits and risks. There may be other options. For more information, visit Toviaz.com.

*Please see accompanying Full Prescribing and Patient Information.*
Toviaz® (fesoterodine fumarate)
For oral administration
Initial U.S. Approval: 2008

INDICATIONS AND USAGE
Toviaz is a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. (1)

DOSAGE AND ADMINISTRATION
The recommended starting dose of Toviaz is 4 mg once daily. Based on individual response and tolerability, the dose may be increased to 8 mg once daily. (2)

The daily dose of Toviaz should not exceed 4 mg in the following populations:
• Patients with severe renal impairment (CLCR < 30 mL/min) (2)
• Patients taking potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, and clarithromycin. (2)
Toviaz is not recommended for use in patients with severe hepatic impairment (Child-Pugh C). (2)
Toviaz should be taken with liquid and swallowed whole. Toviaz can be administered with or without food, and should not be chewed, divided, or crushed. (2)

DOSE FORMS AND STRENGTHS
Toviaz 4 mg extended-release tablets are light blue, oval, biconvex, film-coated, and engraved with “FS” on one side. (3)
Toviaz 8 mg extended-release tablets are blue, oval, biconvex, film-coated, and engraved with “FT” on one side. (3)

CONTRAINDICATIONS
Toviaz is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma. Toviaz is also contraindicated in patients with known hypersensitivity to the drug or its ingredients or to tolterodine tartrate tablets or tolterodine tartrate extended-release capsules. (4)

WARNINGS AND PRECAUTIONS
• Angioedema of the face, lips, tongue, and/or larynx has been reported with fesoterodine. (5.1)
• Toviaz should be administered with caution to patients with clinically significant blader outlet obstruction because of the risk of urinary retention. (5.2)
• Toviaz, like other antimuscarinic drugs, should be used with caution in patients with decreased gastrointestinal motility, such as those with severe constipation. (5.3)
• Toviaz should be used with caution in patients being treated for narrow-angle glaucoma, and only where the potential benefits outweigh the risks (5.4)
• Central Nervous System Effects: Somnolence has been reported with Toviaz. Advise patients not to drive or operate heavy machinery until they know how Toviaz affects them. (5.5)
• Toviaz should be used with caution in patients with myasthenia gravis, a disease characterized by decreased cholinergic activity at the neuromuscular junction. (5.5)

ADVERSE REACTIONS
The most frequently reported adverse events (≥2%) for Toviaz were: dry mouth (placebo, 7%; Toviaz 4 mg, 19%; Toviaz 8 mg, 35%) and constipation (placebo, 2%; Toviaz 4 mg, 4%; Toviaz 8 mg, 6%). (6)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Inc at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DOSAGE FORMS AND STRENGTHS

Dosage and Administration

Indications and Usage

Warnings and Precautions

Adverse Reactions

Full Prescribing Information

Contraindications

Drug Interactions

Full Prescribing Information: Contents*  
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*Sections or subsections omitted from the full prescribing information are not listed.
5.9 Myasthenia Gravis: Toviaz should be used with caution in patients with myasthenia gravis, a disease characterized by decreased cholinergic activity at the neuromuscular junction.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience: The safety of Toviaz was evaluated in Phase 2 and 3 controlled trials in a total of 2859 patients with overactive bladder; of which 2288 were treated with fesoterodine. Of this total, 782 received Toviaz 4 mg/day, and 785 received Toviaz 8 mg/day in Phase 2 or 3 studies with treatment periods of 6 or 12 weeks. Approximately 90% of these patients had >10 weeks exposure to Toviaz in these trials.

A total of 1648 patients participated in two 12-week, Phase 3 efficacy and safety studies and subsequent open-label extension studies. In these two studies combined, 554 patients received Toviaz 4 mg/day and 566 patients received Toviaz 8 mg/day.

In Phase 2 and 3 placebo-controlled trials combined, the incidences of serious adverse events in patients receiving placebo, Toviaz 4 mg, and Toviaz 8 mg were 1.9%, 3.5%, and 2.9%, respectively. All serious adverse events were judged to be not related or unlikely to be related to study medication by the investigator, except for four patients receiving Toviaz who reported one serious adverse event each: angina, chest pain, gastrointestinal, and QT prolongation on ECG. The most commonly reported adverse event in patients treated with Toviaz was dry mouth. The incidence of dry mouth was higher in those taking 8 mg/day (36%) and in those taking 4 mg/day (18%), as compared to placebo (7%). Dry mouth led to discontinuation in 0.4%, 0.4%, and 0.8% of patients receiving placebo, Toviaz 4 mg, and Toviaz 8 mg, respectively. For those patients who reported dry mouth, most had their first occurrence of the event within the first month of treatment.

The second most commonly reported adverse event was constipation. The incidence of constipation was 2% in those taking placebo, 4% in those taking 4 mg/day, and 6% in those taking 8 mg/day.

Table 1 lists adverse events, regardless of causality, that were reported in the combined Phase 2, randomized, placebo-controlled trials at an incidence greater than placebo and in 1% or more of patients treated with Toviaz 4 or 8 mg once daily for up to 12 weeks.

6.2 Post-marketing Experience: The following events have been reported in association with fesoterodine use in worldwide post-marketing experience: Eye disorders: Blurred vision; Cardiac disorders: Palpitations; General disorders and administrative site conditions: Hypersensitivity reactions, including angioedema with airway obstruction, face edema; Central nervous system disorders: Dizziness, headache; Skin and appendages disorders: Urticaria, pruritus.

Because these spontaneously reported events are from the worldwide post-marketing experience, the frequency of events and the role of fesoterodine in their causation cannot be reliably determined.

7 DRUG INTERACTIONS

7.1 Antimuscarinic Drugs: Coadministration of Toviaz with other antimuscarinic agents that produce dry mouth, constipation, urinary retention, and other anticholinergic pharmacological effects may increase the frequency and/or severity of such effects. Anticholinergic agents may potentially alter the absorption of some concomitantly administered drugs due to anticholinergic effects on gastrointestinal motility.

7.2 CYP3A4 Inhibitors: Doses of Toviaz greater than 4 mg are not recommended in patients taking potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, and clarithromycin. Coadministration of the potent CYP3A4 inhibitor ketoconazole with fesoterodine led to approximately a doubling of the maximum concentration (C_max) and area under the concentration versus time curve (AUC) of 5-hydroxymethyl tolterodine (5-HMT), the active metabolite of tofisopam. Compared with CYP3A4 extensive metabolizers, further increases in C_max and AUC of 5-HMT were observed in subjects with CYP3A4 poor metabolizers taking ketoconazole [see Clinical Pharmacology (12.3), Warnings and Precautions (5.8), and Dosage and Administration (2)].

There is no clinically relevant effect of moderate CYP3A4 inhibitors on the pharmacokinetics of fesoterodine. Following blockade of CYP3A4 by coadministration of the moderate CYP3A4 inhibitor fluconazole, the C_max for fesoterodine was increased by 13% and 26%, respectively. The AUC of the active metabolite of fesoterodine was approximately 19% (11% - 28%) and 27% (18% - 36%) respectively. No dosing adjustments are recommended in the presence of moderate CYP3A4 inhibitors (e.g., erlotinib, fluconazole, diltiazem, verapamil and grapefruit juice).

The effect of weak CYP3A4 inhibitors (e.g. cimetidine) was not examined; it is not expected to be in excess of the effect of moderate inhibitors [see Clinical Pharmacology (12.3), Warnings and Precautions (5.8), and Dosage and Administration (2)].

7.3 CYP3A4 Inducers: No dosing adjustments are recommended in the presence of CYP3A4 inducers, such as rifampin and carbamazepine. Following induction of CYP3A4 by coadministration of rifampin 600 mg once a day, C_max and AUC of the active metabolite of fesoterodine decreased by approximately 70% and 75%, respectively, after oral administration of Toviaz 8 mg. The terminal half-life of the active metabolite was not changed.

7.4 CYP2D6 Inhibitors: The effect of CYP2D6 inhibitors on fesoterodine was not tested clinically. In poor metabolizers for CYP2D6, representing a maximum CYP2D6 inhibition, C_max and AUC of the active metabolite were increased 1.7- and 2-fold, respectively.

No dosing adjustments are recommended in the presence of CYP2D6 inhibitors.

7.5 Drugs Metabolized by Cytochrome P450: In vitro data indicate that at therapeutic concentrations, the active metabolite of fesoterodine does not have the potential to inhibit or induce Cytochrome P450 enzyme systems [see Clinical Pharmacology (12.3)].

7.6 Oral Contraceptives: In the presence of fesoterodine, there are no clinically significant changes in the plasma concentrations of combined oral contraceptives containing ethinyl estradiol and levonorgestrel [see Clinical Pharmacology (12.3)].

7.7 Warfarin: A clinical study has shown that fesoterodine 8 mg once daily has no significant effect on the pharmacokinetics or the anticoagulant activity (PT/INR) of warfarin 25 mg. Standard therapeutic monitoring for warfarin should be continued [see Clinical Pharmacology (12.3)].

7.8 Drug-Laboratory Test Interactions: Interactions between Toviaz and laboratory tests have not been studied.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy: Pregnancy Category C. There are no adequate and well-controlled studies using Toviaz in pregnant women.

No dose-related teratogenicity was observed in reproduction studies performed in mice and rabbits. In mice at 6 to 27 times the expected exposure at the maximum recommended human dose (MRHD) of 8 mg based on AUC (75 mg/kg/day, oral), increased resorptions and decreased live fetuses were observed. A fetus with cleft palate was observed at each dose (15, 45, and 75 mg/kg/paw in an incidence similar to the background historical range. In rabbits treated at 3 to 11 times the MRHD (27 mg/kg/day, oral), incompletely ossified sternebrae (retardation of bone development) were observed in fetuses. In rabbits at 9 to 11 times the MRHD (4.5 mg/kg/day, subcutaneous), maternal toxicity and incomplete ossification of sternebrae were observed. In pregnant mice (at an incidence within the background historical range), rabbits at 3 times the MRHD (1.5 mg/kg/day, subcutaneous), decreased maternal food consumption in the absence of any fetal effects was observed. Oral administration of 30 mg/kg/day fesoterodine to mice in a pre- and post-natal development study resulted in decreased body weight of the dams and delayed ear opening of the pups. No effects were noted on mating and reproduction of the F1 generation. Toviaz should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus.

8.3 Nursing Mothers: It is not known whether fesoterodine is excreted in human milk. Toviaz should not be administered during nursing unless the potential benefit outweighs the potential risk to the neonate.

8.4 Pediatric Use: The pharmacokinetics of fesoterodine have not been evaluated in pediatric patients. The safety and effectiveness of Toviaz in pediatric patients have not been established.

8.5 Geriatric Use: No dose adjustment is recommended for the elderly. The pharmacokinetics of fesoterodine are not significantly influenced by age.

Of 1567 patients who received Toviaz 4 mg/day or 8 mg/day in the Phase 2 and 3, placebo-controlled, efficacy and safety studies, 515 (33%) were 65 years of age or older, and 140 (9%) were 75 years of age or older. No overall differences in safety or effectiveness were observed between patients younger than 65 years of age and those 65 years of age or older in these studies; however, the incidence of an adverse event, including dry mouth, constipation, urinary retention, and dry eyes, was slightly greater in patients 75 years of age and older as compared to younger patients [see Clinical Studies (14) and Adverse Reactions (6)].

8.6 Renal Impairment: In patients with severe renal impairment (CL CR < 30 mL/min), C_max and AUC are increased 2.0- and 2.3-fold, respectively. Doses of Toviaz greater than 4 mg are not recommended in patients with severe renal impairment. C_max and AUC of fesoterodine are increased up to 1.5- and 1.8-fold, respectively, as compared to healthy subjects. No dose adjustment is recommended in patients with mild or moderate renal impairment [see Warnings and Precautions (5.7) and Dosage and Administration (2)].

8.7 Hepatic Impairment: Patients with severe hepatic impairment (Child-Pugh C) have not been studied; therefore Toviaz is not recommended for use in these patients. In patients with moderate (Child-Pugh B) hepatic impairment, C_max and AUC of the active metabolite are increased 1.4- and 2.1-fold, respectively, as compared to healthy subjects. No dose adjustment is recommended in patients with mild or moderate hepatic impairment [see Warnings and Precautions (5.6) and Dosage and Administration (2)].

8.8 Gender: No dose adjustment is recommended based on gender. The pharmacokinetics of fesoterodine are not significantly influenced by gender.

8.9 Race: Available data indicate that there are no differences in the pharmacokinetics of fesoterodine between Caucasian and black healthy subjects following administration of Toviaz.

10 OVERDOSAGE

Overdosage with Toviaz can result in severe anticholinergic effects. Treatment should be symptomatic and supportive. In the event of overdose, ECG monitoring is recommended.
11 DESCRIPTION

Toviaz contains fesoterodine fumarate and is an extended-release tablet. Fesoterodine is rapidly de-esterified to its active metabolite (R)-2-(3-diisopropylaminol-1-phenylpropyl)-4-hydroxyethylphenyl, or 5-hydroxyethyl tolterodine, which is a muscarinic receptor antagonist.

Chemically, fesoterodine fumarate is designated as isobutyric acid 2-((R)-3-diisopropylammonium-1-phenylpropyl)-4-(hydroxyethyl) phenyl ester hydrogen fumarate. The empirical formula is C30H41NO7 and its molecular weight is 527.66. The structural formula is:

The asterisk (*) indicates the chiral carbon.

Fesoterodine fumarate is a white to off-white powder, which is freely soluble in water. Each Toviaz extended-release tablet contains either 4 mg or 8 mg of fesoterodine fumarate and the following inactive ingredients: lactose, 3-5% 5-9% 11% 12% 13% 14% 15% 16% 17% 18% 19% 20% 21% 22% 23% 24% 25% 26% 27% 28% 29% 30% 31% 32% 33% 34% 35% 36% 37% 38% 39% 40% 41% 42% 43% 44% 45% 46% 47% 48% 49% 50% 51% 52% 53% 54% 55% 56% 57% 58% 59% 60% 61% 62% 63% 64% 65% 66% 67% 68% 69% 70% 71% 72% 73% 74% 75% 76% 77% 78% 79% 80% 81% 82% 83% 84% 85% 86% 87% 88% 89% 90% 91% 92% 93% 94% 95% 96% 97% 98% 99% 100%
Compared to warfarin alone dosing, the Cmax and AUC of S-warfarin were lower by ~4%, while the Cmax and AUC of R-warfarin were lower by approximately 8% and 6% for the co-administration, suggesting absence of a significant pharmacokinetic interaction.

There were no statistically significant changes in the measured pharmacodynamic parameters for anti-coagulant activity of warfarin (INR_{max, AUC_{INR}}), with only a small decrease noted in INR_{max} of ~3% with the co-administration relative to warfarin alone. INR versus time profiles across individual subjects in the study suggested some differences following co-administration with fesoterodine, although there was no definite trend with regard to the changes noted [see Drug Interactions (7.7)].

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility: No evidence of drug-related carcinogenicity was found in 24-month studies with oral administration to mice and rats. The highest tolerated doses in mice (females 45 to 60 mg/kg/day, males 30 to 45 mg/kg/day) corresponded to 11 to 19 times (females) and 4 to 9 times (males) the estimated human AUC values reached with fesoterodine 8 mg, which is the Maximum Recommended Human Dose (MRHD). In rats, the highest tolerated dose (45 to 60 mg/kg/day) corresponds to 3 to 8 times (females) and 3 to 14 times (males) the estimated human AUC at the MRHD.

Fesoterodine was not mutagenic or genotoxic in vitro (Ames tests, chromosome aberration tests) or in vivo (mouse micronucleus test).

Fesoterodine had no effect on reproductive function, fertility, or early embryonic development of the fetus at non-maternally toxic doses in mice. The maternal No-observed-Effect Level (NOEL) and the NOEL for effects on reproduction and early embryonic development were both 15 mg/kg/day. Based on AUC, the systemic exposure was 0.6 to 1.5 times higher in mice than in humans at the MRHD, whereas based on peak plasma concentrations, the exposure in mice was 5 to 9 times higher. The Lowest-Observed-Effect Level (LOEL) for maternal toxicity was 45 mg/kg/day.

14 CLINICAL STUDIES

Toviaz extended-release tablets were evaluated in two, Phase 3, randomized, double-blind, placebo-controlled, 12-week studies for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. Entry criteria required that patients have symptoms of overactive bladder for ≥6-months duration, at least 8 micturitions per day, and at least 6 urinary urgency episodes or 2 urge incontinence episodes per 3-day diary period. Patients were randomized to a fixed dose of Toviaz 4 or 8 mg/day or placebo. In one of these studies, 290 patients were randomized to an active control arm (an oral antimuscarinic agent). For the combined studies, a total of 554 patients received placebo, 554 patients received Toviaz 4 mg/day, and 566 patients received Toviaz 8 mg/day. The majority of patients were Caucasian (91%) and female (79%) with a mean age of 58 years (range 19-91 years).

The primary efficacy endpoints were the mean change in the number of urge urinary incontinence episodes per 24 hours and the mean change in the number of micturitions (frequency) per 24 hours. An important secondary endpoint was the mean change in the voided volume per micturition.

Results for the primary endpoints and for mean change in voided volume per micturition from the two 12-week clinical studies of Toviaz are reported in Table 3.

### Table 3: Mean baseline and change from baseline to Week 12 for urge urinary incontinence episodes, number of micturitions, and volume voided per micturition

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Study 1</th>
<th>Study 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Placebo</td>
<td>Toviaz 4mg/day</td>
</tr>
<tr>
<td>Number of urge incontinence episodes per 24 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>3.7</td>
<td>3.8</td>
</tr>
<tr>
<td>Change from baseline</td>
<td>-1.20</td>
<td>-2.06</td>
</tr>
<tr>
<td>p-value vs. placebo</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Number of micturitions per 24 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>12.0</td>
<td>12.1</td>
</tr>
<tr>
<td>Change from baseline</td>
<td>-1.02</td>
<td>-1.14</td>
</tr>
<tr>
<td>p-value vs. placebo</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Voided volume per micturition (mL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>150</td>
<td>160</td>
</tr>
<tr>
<td>Change from baseline</td>
<td>10</td>
<td>27</td>
</tr>
<tr>
<td>p-value vs. placebo</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

vs. = versus

*Only those patients who were urge incontinent at baseline were included for the analysis of number of urge incontinence episodes per 24 hours in Study 1, the number of these patients was 211, 199, and 223 in the placebo, Toviaz 4 mg/day and Toviaz 8 mg/day groups, respectively. In Study 2, the number of these patients was 205, 228, and 218, respectively."

Figures 1-4: The following figures show change from baseline over time in number of micturitions and urge urinary incontinence episodes per 24 h in the two studies.

Figure 1: Change in Number of Micturitions per 24 h (Study 1)

Figure 2: Change in Urge Incontinence Episodes per 24 h (Study 1)

Figure 3: Change in Number of Micturitions per 24 h (Study 2)

Figure 4: Change in Urge Incontinence Episodes per 24 h (Study 2)

A reduction in number of urge urinary incontinence episodes per 24 hours was observed for both doses as compared to placebo as early as two weeks after starting Toviaz therapy.

16 HOW SUPPLIED/STORAGE AND HANDLING

Toviaz (fesoterodine fumarate) extended-release tablets 4 mg are light blue, oval, biconvex, film-coated, and engraved with "FS" on one side. They are supplied as follows:

- Bottles of 30 NDC 0069-0242-30 Toviaz (fesoterodine fumarate) extended-release tablets 8 mg are blue, oval, biconvex, film-coated, and engraved with "FT" on one side. They are supplied as follows:
  - Bottles of 30 NDC 0069-0244-30

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Protect from moisture.

17 PATIENT COUNSELING INFORMATION

See FDA-Approved Patient Labeling (17.2)

17.1 Information for Patients: Patients should be informed that fesoterodine may produce angioedema, which could result in life-threatening airway obstruction. Patients should be advised to promptly discontinue fesoterodine therapy and seek immediate medical attention if they experience edema of the tongue or laryngopharynx, or difficult breathing.

Patients should be informed that Toviaz, like other antimuscarinic agents, may produce clinically significant adverse effects related to antimuscarinic pharmacological activity including constipation and urinary retention. Toviaz, like other antimuscarinics, may be associated with blurred vision, therefore, patients should be advised to exercise caution in decisions to engage in potentially dangerous activities until the drug’s effects on the patient have been determined. Heat prostration (due to decreased sweating) can occur when Toviaz, like other antimuscarinic drugs, is used in a hot environment.

Patients should also be informed that alcohol may enhance the drowsiness caused by Toviaz, like other anticholinergic agents. Patients should read the patient leaflet entitled “Patient Information TOVIAZ” before starting therapy with Toviaz.
Patient Information

TOVIAZ® (TOH-vee-as)
(fesoterodine fumarate)
extended-release tablets

Read the Patient Information that comes with TOVIAZ before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or your treatment.

What is TOVIAZ?
TOVIAZ is a prescription medicine used in adults to treat symptoms of a condition called overactive bladder, including:
- Urge urinary incontinence -- leaking or wetting accidents due to a strong need to urinate,
- Urinary urgency -- having a strong need to urinate right away,
- Urinary frequency -- having to urinate too often.

TOVIAZ has not been studied in children.

Who should not take TOVIAZ?
Do not take TOVIAZ if you:
- Are not able to empty your bladder (urinary retention)
- Have delayed or slow emptying of your stomach (gastric retention)
- Have an eye problem called "uncontrolled narrow-angle glaucoma"
- Are allergic to TOVIAZ or any of its ingredients. See the end of this leaflet for a complete list of ingredients
- Are allergic to Detrol® or Detrol® LA, which contains tolterodine.

What should I tell my doctor before starting TOVIAZ?
Before starting TOVIAZ, tell your doctor about all of your medical and other conditions that may affect the use of TOVIAZ, including:
- Stomach or intestinal problems or problems with constipation
- Problems emptying your bladder or if you have a weak urine stream
- Treatment for an eye problem called narrow-angle glaucoma
- Kidney problems
- Liver problems
- A condition called myasthenia gravis
- If you are pregnant or trying to become pregnant. It is not known if TOVIAZ can harm your unborn baby.
- If you are breastfeeding. It is not known if TOVIAZ passes into breast milk or if it can harm your baby. Talk to your doctor about the best way to feed your baby if you take TOVIAZ.

Before starting on TOVIAZ, tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal products. TOVIAZ may affect the way other medicines work, and other medicines may affect how TOVIAZ works. Especially tell your doctor if you are taking antibiotics or antifungal medicines.

Know all the medicines you take. Keep a list of them with you to show your doctor and pharmacist each time you get a new medicine.

How should I take TOVIAZ?
- Take TOVIAZ exactly as your doctor tells you to take it.
- 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 with liquid and swallow the tablet whole. Do not chew, divide, or crush the tablet.
- You can take TOVIAZ with or without food.
- If you miss a dose of TOVIAZ, begin taking TOVIAZ again the next day. Do not take 2 doses of TOVIAZ in the same day.

If you take too much TOVIAZ, call your doctor or go to an emergency department right away.

What are the possible side effects of TOVIAZ?
TOVIAZ may cause allergic reactions that may be serious. Symptoms of a serious allergic reaction may include swelling of the face, lips, throat or tongue. If you experience these symptoms, you should stop taking TOVIAZ and get emergency medical help right away.

The most common side effects of TOVIAZ are:
- Dry mouth
- Constipation

TOVIAZ may cause other less common side effects, including:
- Dry eyes
- Trouble emptying the bladder

Tell your doctor if you have any side effects that bother you or that do not go away. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

These are not all of the possible side effects of TOVIAZ. For a complete list, ask your doctor.

What else should I keep in mind while taking TOVIAZ?
- Do not drive, operate machinery, or do other dangerous activities until you know how TOVIAZ affects you. Blurred vision, dizziness, and drowsiness are possible side effects of medicines such as TOVIAZ.
- Use caution in hot environments. Decreased sweating and severe heat illness can occur when medicines such as TOVIAZ are used in a hot environment.
- Drinking alcohol while taking medicines such as TOVIAZ may cause increased drowsiness.

How should I store TOVIAZ?
- Store TOVIAZ at room temperature, 68° to 77°F (20° to 25°C); brief periods permitted between 59° to 86°F (15° to 30°C)
- Protect the medicine from moisture by keeping the bottle closed tightly.
- Safely throw away TOVIAZ that is out of date or no longer needed.

Keep TOVIAZ and all medicines out of the reach of children.

General information about TOVIAZ
Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Only use TOVIAZ the way your doctor tells you. Do not give TOVIAZ to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about TOVIAZ. If you would like more information, talk with your doctor. You can ask your doctor for information about TOVIAZ that is written for healthcare professionals. You can also call 1-877-9-TOVIAZ (1-877-986-8429) or go to www.TOVIAZ.com.

What are the ingredients in TOVIAZ?
Active ingredient: fesoterodine fumarate
Inactive ingredients: glyceryl behenate, hypromellose, indigo carmine aluminum lake, lactose monohydrate, soya lecithin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide, and xylitol.

This product's label may have been updated. For current full prescribing information, please visit www.pfizer.com.

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