Introducing TOVIAZ and the *YourWay*™ Plan

TOVIAZ is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

Get the Full Picture in OAB Care

Toviaz™
fesoterodine fumarate
extended release tablets 4mg and 8mg

Please see full prescribing and patient information on last pages.

Understanding the Impact of Overactive Bladder (OAB)

TOVIAZ treats the physical symptoms

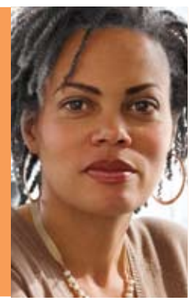
Common Physical Symptoms[1,2]

- Urgency
- Urge urinary incontinence (UUI)
- Frequency

For patients with OAB, there are other factors to consider

Behavioral and Coping Habits[3,4]

- Limiting physical activities
- Bathroom mapping
- Wearing incontinence pads



The Emotional Impact[3-5]

- Feeling embarrassed
- Worry about loss of bladder control
- Limiting social situations

The *YourWay*™ plan was designed to help educate patients about how to take a more active role in their care

TOVIAZ is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

New TOVIAZ:
Available in 2 Dose Strengths

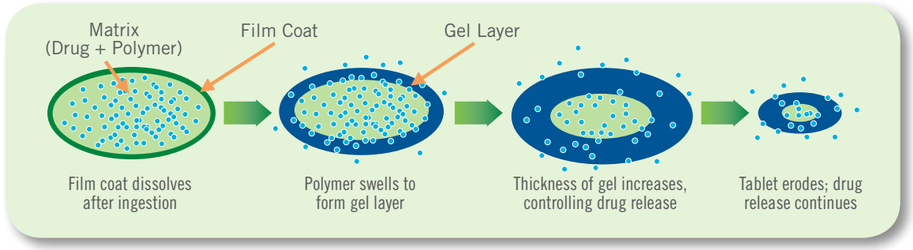
Fesoterodine is rapidly and extensively converted to its active metabolite, 5-HMT,* which is also the active metabolite of tolterodine[6]

Dosing flexibility with 4 mg and 8 mg tablets

Recommended starting dose:	Based on individual response/ tolerability, dose may be increased to:
TOVIAZ 4 mg	TOVIAZ 8 mg

The daily dose of TOVIAZ should not exceed 4 mg in patients with severe renal insufficiency and in patients taking potent CYP3A4 inhibitors such as ketoconazole, itraconazole, and clarithromycin. TOVIAZ is not recommended for use in patients with severe hepatic impairment.

TOVIAZ offers an extended-release mechanism for once-daily dosing[7]



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.

*5-HMT=5 hydroxymethyl tolterodine.

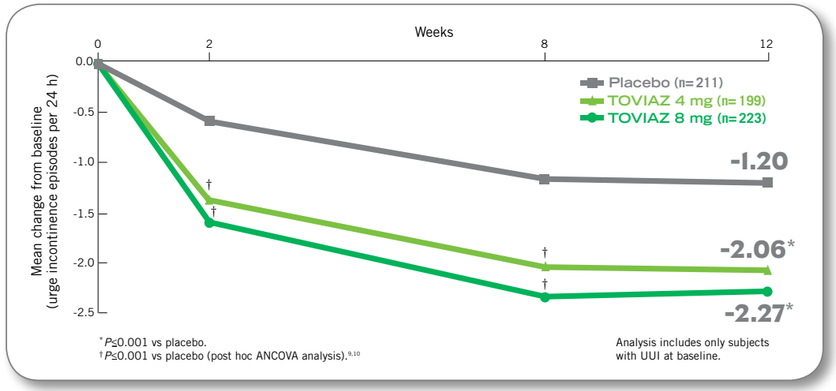
TOVIAZ is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma and in patients with known hypersensitivity to the drug or its ingredients.

Please see full prescribing and patient information on last pages.

Toviaz™
fesoterodine fumarate
extended release tablets 4mg and 8mg

Focus on Efficacy:
Significant Reductions in OAB Symptoms

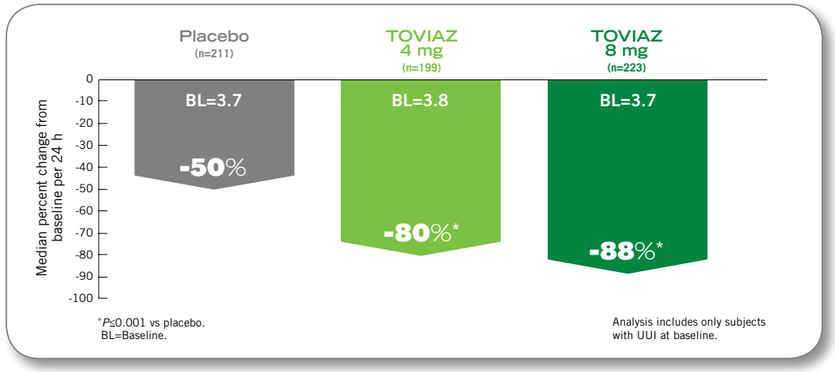
TOVIAZ significantly reduced UUI episodes over time[8]



Mean UUI episodes per day at baseline: 3.7 for placebo, 3.8 for TOVIAZ 4 mg, and 3.7 for TOVIAZ 8 mg.

A 12-week, randomized, double-blind, placebo- and active-controlled international ex-US study to assess the efficacy, tolerability, and safety of TOVIAZ in adults with OAB. Subjects (N=1132) were treated once daily with placebo, TOVIAZ 4 mg or 8 mg, or an active-control agent (an oral antimuscarinic).[11]

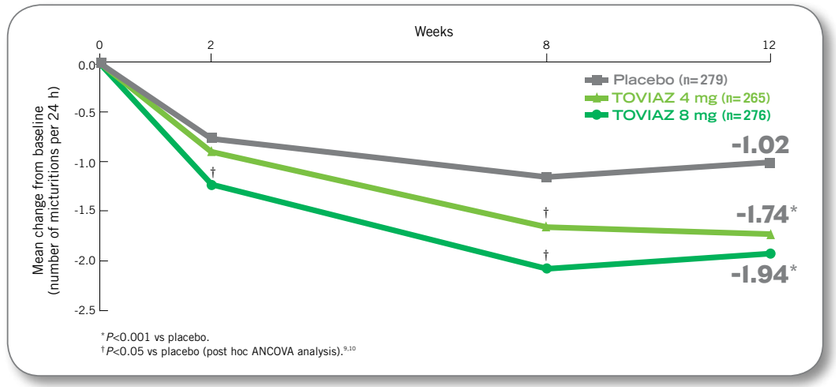
TOVIAZ significantly reduced UUI episodes at Week 12[11]



- In a similar study conducted in the US (N=832), the median percent reduction in UUI episodes at Week 12 was also significantly greater with TOVIAZ than with placebo (40%, 67%, and 82% for placebo, TOVIAZ 4 mg, and TOVIAZ 8 mg, respectively [*P*<0.001])[12]
- The recommended starting dose of TOVIAZ is 4 mg once daily. Based upon individual response and tolerability, the dose may be increased to 8 mg once daily. Please see page 3 for full dosing guidelines.

TOVIAZ tablets should be used with caution in patients with clinically significant bladder outlet obstruction, decreased gastrointestinal motility, controlled narrow-angle glaucoma, myasthenia gravis, and significantly reduced hepatic or renal function. TOVIAZ is not recommended for use in patients with severe hepatic impairment.

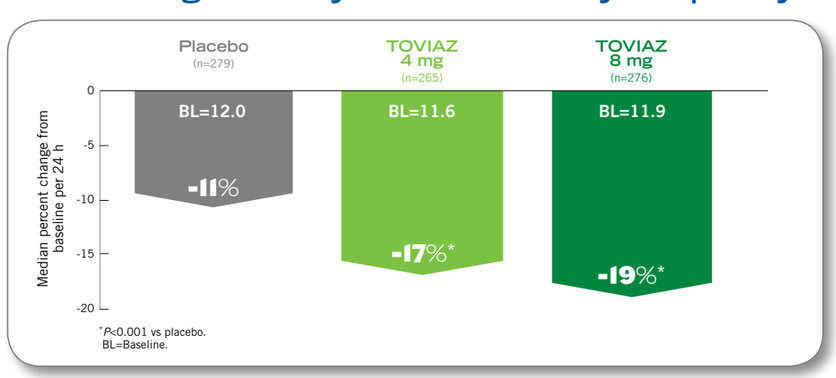
TOVIAZ significantly reduced urinary frequency over time[13]



Mean urinary frequency per day at baseline: 12.0 for placebo, 11.6 for TOVIAZ 4 mg, and 11.9 for TOVIAZ 8 mg.

A 12-week, randomized, double-blind, placebo- and active-controlled international ex-US study to assess the efficacy, tolerability, and safety of TOVIAZ in adults with OAB. Subjects (N=1132) were treated once daily with placebo, TOVIAZ 4 mg or 8 mg, or an active-control agent (an oral antimuscarinic).[11]

TOVIAZ significantly reduced urinary frequency at Week 12[11]



- In a similar study conducted in the US (N=832), the median percent reduction in urinary frequency at Week 12 was also significantly greater with TOVIAZ than with placebo (7%, 15%, and 16% for placebo, TOVIAZ 4 mg, and TOVIAZ 8 mg, respectively [*P*<0.001])[12]

The most frequently reported adverse events (≥4%) 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%).

Toviaz™
fesoterodine fumarate
extended release tablets 4mg and 8mg

Please see full prescribing and patient information on last pages.

Focus on Tolerability:
Side Effect Profile

3 YEAR DATA

three open-label clinical studies support long-term tolerability and safety profiles

- In these open-label extensions of one Phase 2 and two Phase 3 trials, all subjects (N=890) were started on TOVIAZ 8 mg and could reduce to TOVIAZ 4 mg at 1 month (TOVIAZ 8 mg could be resumed at any visit)[14,15]
  - **At least 80% of continuing subjects remained on TOVIAZ 8 mg at every visit**
  - **16% chose to decrease to 4 mg at 1 month**

In 12-week clinical trials

CNS side effects were low and similar to placebo[16]

	Placebo (n=554)	TOVIAZ 4 mg (n=554)	TOVIAZ 8 mg (n=566)
Headache	4.2%	4.3%	2.7%
Dizziness	2.0%	1.3%	1.1%
Insomnia	0.5%	1.3%	0.4%
Fatigue	0.5%	0.9%	0.4%
Blurred vision	0.9%	0.2%	0.5%

TOVIAZ tablets should be used with caution in patients with clinically significant bladder outlet obstruction, decreased gastrointestinal motility, controlled narrow-angle glaucoma, myasthenia gravis, and significantly reduced hepatic or renal function. TOVIAZ is not recommended for use in patients with severe hepatic impairment.

Tolerability and safety profiles in 12-week clinical trials

Incidence of dry mouth[17]

	Placebo (n=554)	TOVIAZ 4 mg (n=554)	TOVIAZ 8 mg (n=566)
Dry mouth	7%	19%	35%
Mild	5%	15%	23%
Moderate	2%	3%	9%
Severe	<1%	1%	3%

- Fewer than 1% of patients discontinued due to dry mouth

Incidence of constipation

	Placebo (n=554)	TOVIAZ 4 mg (n=554)	TOVIAZ 8 mg (n=566)
Constipation	2%	4%	6%

- Constipation is a common problem in the elderly[18] that can worsen OAB[19]

TOVIAZ is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma and in patients with known hypersensitivity to the drug or its ingredients.

Please see full prescribing and patient information on last pages.

Toviaz™
fesoterodine fumarate
extended release tablets 4mg and 8mg

Expanding the Perspective on Patient Management

There are other factors to consider for patients with OAB

Behavioral and Coping Habits[3,4]

Emotional Impact[3-5]

An important part of treatment can be patient education about behavioral changes,[19,20] such as...

- ✓ **Healthy dietary habits** to help patients learn which foods and liquids can irritate the bladder[20,21]
- ✓ **Altering fluid intake** throughout the day as an important strategy for patients to learn[22,23]
- ✓ **Bladder diaries** to help patients learn to track their progress[24-27]
- ✓ **Bladder training** to help patients learn how to reduce incontinence episodes and extend time between voids[26,28,29]
- ✓ **Pelvic floor muscle training** (ie, Kegel exercises) to help patients learn how to strengthen muscles and suppress urgency[22,30,31]
- ✓ **Weight management** to help patients understand how weight can affect their condition[32,33]

TOVIAZ tablets should be used with caution in patients with clinically significant bladder outlet obstruction, decreased gastrointestinal motility, controlled narrow-angle glaucoma, myasthenia gravis, and significantly reduced hepatic or renal function. TOVIAZ is not recommended for use in patients with severe hepatic impairment.

Only TOVIAZ Comes With the *YourWay*™ Plan

The plan designed to help empower your patients to take an active role in their OAB treatment

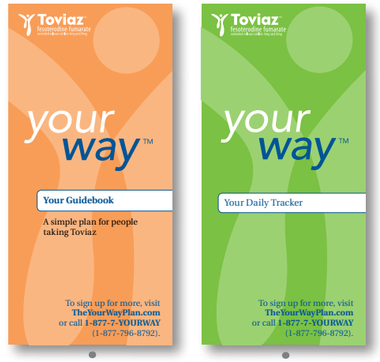
Provides key information that patients need to get started

Included with the sample package!

The 4 Components of the *YourWay* Plan

Dietary habits
Helps patients understand why it is important to make informed diet choices

Training techniques
Teaches patients timed voiding, urgency suppression, and pelvic floor muscle training



Tracking
Helps patients track their progress with the plan and share with their physician

Daily TOVIAZ
Explains how medication works and what to expect from therapy

The *YourWay* plan **Guidebook** explains the 4 components and why they are important

The *YourWay* plan **Daily Tracker** aims to help patients stay engaged in the plan over a 12-week period

The *YourWay* plan provides an additional level of support

Patients can register for added support provided by phone, or , or direct mail over a 12-week period to learn what to expect from treatment, strategies to incorporate positive behavioral changes, and how to track their progress with the plan.

Toviaz™
fesoterodine fumarate
extended release tablets 4mg and 8mg

Please see full prescribing and patient information on last pages.

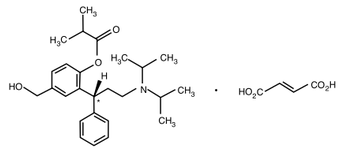
TOVIAZ™

(fesoterodine fumarate)
extended-release tablets
Rx only
Prescribing Information

DESCRIPTION

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

Chemically, fesoterodine fumarate is designated as isobutyric acid 2-((R)-3-diisopropylammonium-1-phenylpropyl)-4-(hydroxymethyl) phenyl ester hydrogen fumarate. The empirical formula is $C_{36}H_{41}NO_7$ 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: glyceryl behenate, hypromellose, indigo carmine aluminum lake, lactose monohydrate, soya lecithin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide, and xylitol.

CLINICAL PHARMACOLOGY

Fesoterodine is a competitive muscarinic receptor antagonist. After oral administration, fesoterodine is rapidly and extensively hydrolyzed by nonspecific esterases to its active metabolite, 5-hydroxymethyl tolterodine, which is responsible for the antimuscarinic activity of fesoterodine.

Muscarinic receptors play a role in contractions of urinary bladder smooth muscle and stimulation of salivary secretion. Inhibition of these receptors in the bladder is presumed to be the mechanism by which fesoterodine produces its effects.

Pharmacodynamics

In a urodynamic study involving patients with involuntary detrusor contractions, the effects after the administration of fesoterodine on the volume at first detrusor contraction and bladder capacity were assessed. Administration of fesoterodine increased the volume at first detrusor contraction and bladder capacity in a dose-dependent manner. These findings are consistent with an antimuscarinic effect on the bladder.

Pharmacokinetics

Absorption

After oral administration, fesoterodine is well absorbed. Due to rapid and extensive hydrolysis by nonspecific esterases to its active metabolite, fesoterodine cannot be detected in plasma. Bioavailability of the active metabolite is 52%. After single or multiple-dose oral administration of fesoterodine in doses from 4 mg to 28 mg, plasma concentrations of the active metabolite are proportional to the dose. Maximum plasma levels are reached after approximately 5 hours. No accumulation occurs after multiple-dose administration.

A summary of pharmacokinetic parameters for the active metabolite after a single dose of Toviaz 4 mg and 8 mg in extensive and poor metabolizers of CYP2D6 is provided in Table 1.

Table 1 Summary of geometric mean [CV] pharmacokinetic parameters for the active metabolite after a single dose of Toviaz 4 mg and 8 mg in extensive and poor CYP2D6 metabolizers

	Toviaz 4 mg		Toviaz 8 mg	
Parameter	**EM (n=16)**	**PM (n=8)**	**EM (n=16)**	**PM (n=8)**
C_{max} (ng/mL)	1.89 [43%]	3.45 [54%]	3.98 [28%]	6.90 [39%]
$AUC_{0\text{-}tz}$ (ng*h/mL)	21.2 [38%]	40.5 [31%]	45.3 [32%]	88.7 [36%]
t_{max} (h)[a]	5 [2-6]	5 [5-6]	5 [3-6]	5 [5-6]
$t_{1/2}$ (h)	7.31 [27%]	7.31 [30%]	8.59 [41%]	7.66 [21%]

EM = extensive CYP2D6 metabolizer, PM = poor CYP2D6 metabolizer, CV=coefficient of variation

C_{max} = maximum plasma concentration, $AUC_{0\text{-}tz}$ = area under the concentration time curve from zero up to the last measurable plasma concentration, t_{max} = time to reach C_{max}, $t_{1/2}$= terminal half-life

[a] Data presented as median (range)

Effect of Food

There is no clinically relevant effect of food on the pharmacokinetics of fesoterodine. (see DOSAGE AND ADMINISTRATION)

Distribution

Plasma protein binding of the active metabolite is low (approximately 50%) and is primarily bound to albumin and alpha-1-acid glycoprotein. The mean steady-state volume of distribution following intravenous infusion of the active metabolite is 169 L.

Metabolism

After oral administration, fesoterodine is rapidly and extensively hydrolyzed to its active metabolite. The active metabolite is further metabolized in the liver to its carboxy, carboxy-N-desisopropyl, and N-desisopropyl metabolites via two major pathways involving CYP2D6 and CYP3A4. None of these metabolites contribute significantly to the antimuscarinic activity of fesoterodine.

Variability in Metabolism: A subset of individuals (approximately 7% Caucasians and 2% African Americans) are poor metabolizers for CYP2D6. The remainder of the population is referred to as extensive metabolizers. C_{max} and AUC of the active metabolite are increased 1.7- and 2-fold, respectively, in CYP2D6 poor metabolizers as compared to extensive metabolizers.

Excretion

Hepatic metabolism and renal excretion contribute significantly to the elimination of the active metabolite. After oral administration of fesoterodine, approximately 70% of the administered dose was recovered in urine as the active metabolite (16%), carboxy metabolite (34%), carboxy-N-desisopropyl metabolite (18%), or N-desisopropyl metabolite (1%), and a smaller amount (7%) was recovered in feces.

The terminal half-life of the active metabolite is approximately 4 hours following an intravenous administration. The apparent terminal half-life following oral administration is approximately 7 hours.

Pharmacokinetics in Special Populations

Age

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

Pediatric

The pharmacokinetics of fesoterodine have not been evaluated in pediatric patients.

Gender

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

Race

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

Renal Insufficiency

In patients with mild or moderate renal insufficiency (CL_{CR} ranging from 30-80 mL/min), C_{max} and AUC of the active metabolite are increased up to 1.5- and 1.8-fold respectively, as compared to healthy subjects. In patients with severe renal insufficiency (CL_{CR} < 30 mL/min), C_{max} and AUC are increased 2.0- and 2.3-fold, respectively.

In patients with mild or moderate renal insufficiency, no dose adjustment is recommended. Doses of Toviaz greater than 4 mg are not recommended in patients with severe renal insufficiency (see PRECAUTIONS and DOSAGE AND ADMINISTRATION).

Hepatic Impairment

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. Subjects with severe hepatic impairment (Child-Pugh C) have not been studied; therefore Toviaz is not recommended for use in these patients (see PRECAUTIONS and DOSAGE AND ADMINISTRATION).

Drug-Drug Interactions

Drugs Metabolized by Cytochrome P450

At therapeutic concentrations, the active metabolite of fesoterodine does not inhibit CYP1A2, 2B6, 2C8, 2C9, 2C19, 2D6, 2E1, or 3A4, or induce CYP1A2, 2B6, 2C9, 2C19, or 3A4 in vitro.

CYP3A4 Inhibitors

Following blockade of CYP3A4 by coadministration of the potent CYP3A4 inhibitor ketoconazole 200 mg twice a day for 5 days, C_{max} and AUC of the active metabolite of fesoterodine increased 2.0- and 2.3-fold, respectively, after oral administration of Toviaz 8 mg to CYP2D6 extensive metabolizers. In CYP2D6 poor metabolizers, C_{max} and AUC of the active metabolite of fesoterodine increased 2.1- and 2.5-fold, respectively, during co-administration of ketoconazole 200 mg twice a day for 5 days. C_{max} and AUC were 4.5- and 5.7-fold higher, respectively, in subjects who were CYP2D6 poor metabolizers and taking ketoconazole compared to subjects who were CYP2D6 extensive metabolizers and not taking ketoconazole. In a separate study coadministering fesoterodine with ketoconazole 200 mg once a day for 5 days, the C_{max} and AUC values of the active metabolite of fesoterodine were increased 2.2-fold in CYP2D6 extensive metabolizers and 1.5- and 1.9-fold, respectively, in CYP2D6 poor metabolizers. C_{max} and AUC were 3.4- and 4.2-fold higher, respectively, in subjects who were CYP2D6 poor metabolizers and taking ketoconazole compared to subjects who were CYP2D6 extensive metabolizers and not taking ketoconazole.

Therefore, doses of Toviaz greater than 4mg are not recommended in patients taking potent CYP3A4 inhibitors, such as ketoconazole, itraconazole and clarithromycin (see PRECAUTIONS, Drug Interactions and DOSAGE and ADMINISTRATION).

The effects of weak or moderate CYP3A4 inhibitors were not examined.

CYP3A4 Inducers

Following induction of CYP3A4 by coadministration of rifampicin 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.

Induction of CYP3A4 may lead to reduced plasma levels. No dosing adjustments are recommended in the presence of CYP3A4 inducers.

CYP2D6 Inhibitors

The interaction with CYP2D6 inhibitors was not tested clinically. In poor metabolizers for CYP2D6, representing a maximum CYP2D6 inhibition, C_{max} and AUC of the active metabolite are increased 1.7- and 2-fold, respectively.

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

Oral Contraceptives

In the presence of fesoterodine, there are no changes in the plasma concentrations of combined oral contraceptives containing ethinyl estradiol and levonorgestrel.

Cardiac Electrophysiology

The effect of fesoterodine 4 mg and 28 mg on the QT interval was evaluated in a double-blind, randomized, placebo- and positive-controlled (moxifloxacin 400 mg once a day) parallel trial with once-daily treatment over a period of 3 days in 261 male and female subjects aged 44 to 65 years. Electrocardiographic parameters were measured over a 24-hour period at pre-dose, after the first administration, and after the third administration of study medication. Fesoterodine 28 mg was chosen because this dose, when administered to CYP2D6 extensive metabolizers, results in an exposure to the active metabolite that is similar to the exposure in a CYP2D6 poor metabolizer receiving fesoterodine 8 mg together with CYP3A4 blockade. Corrected QT intervals (QTc) were calculated using Fridericia's correction and a linear individual correction method. Analyses of 24-hour average QTc, time-matched baseline-corrected QTc, and time-matched placebo-subtracted QTc intervals indicate that fesoterodine at doses of 4 and 28 mg/day did not prolong the QT interval. The sensitivity of the study was confirmed by positive QTc prolongation by moxifloxacin.

Toviaz is associated with an increase in heart rate that correlates with increasing dose. In the study described above, when compared to placebo, the mean increase in heart rate associated with a dose of 4 mg/day and 28 mg/day of fesoterodine was 3 beats/minute and 11 beats/minute respectively.

In the two, phase 3, placebo-controlled studies in patients with overactive bladder, the mean increase in heart rate compared to placebo was approximately 3-4 beats/minute in the 4 mg/day group and 3-5 beats/minute in the 8 mg/day group.

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 3 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 2.

Table 2 Mean baseline and change from baseline to Week 12 for urge urinary incontinence episodes, number of micturitions, and volume voided per micturition

	Study 1			Study 2		
Parameter	**Placebo N=279**	**Toviaz 4mg/day N=265**	**Toviaz 8mg/day N=276**	**Placebo N=266**	**Toviaz 4mg/day N=267**	**Toviaz 8mg/day N=267**
Number of urge incontinence episodes per 24 hours[a]						
Baseline	3.7	3.8	3.7	3.7	3.9	3.9
Change from baseline	-1.20	-2.06	-2.27	-1.00	-1.77	-2.42
p-value vs placebo	-	0.001	<0.001	-	<0.003	<0.001
Number of micturitions per 24 hours						
Baseline	12.0	11.6	11.9	12.2	12.9	12.0
Change from baseline	-1.02	-1.74	-1.94	-1.02	-1.86	-1.94
p-value vs placebo	-	<0.001	<0.001	-	0.032	<0.001
Voided volume per micturition (mL)						
Baseline	150	160	154	159	152	156
Change from baseline	10	27	33	8	17	33
p-value vs placebo	-	<0.001	<0.001	-	0.150	<0.001

vs=versus

a 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)

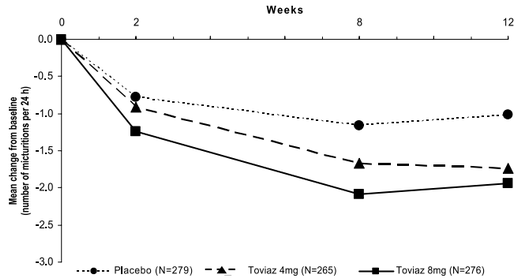


Figure 2: Change in Urge Incontinence Episodes per 24 h (Study 1)

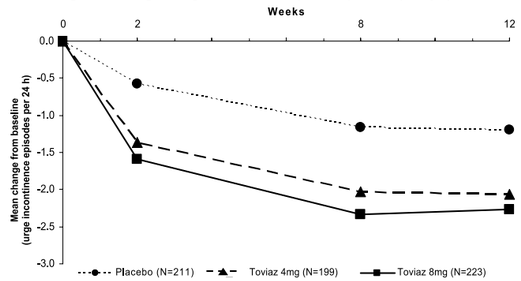


Figure 3: Change in Number of Micturitions per 24 h (Study 2)

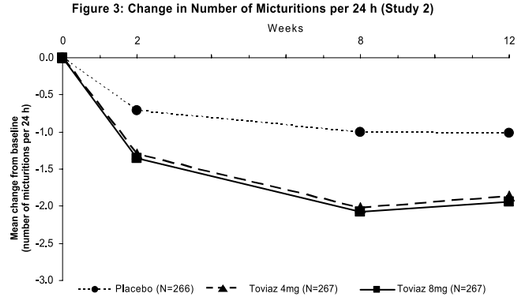
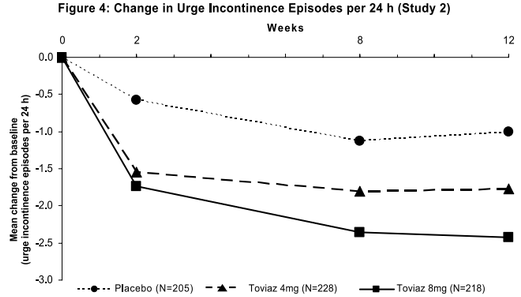


Figure 4: Change in Urge Incontinence Episodes per 24 h (Study 2)



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.

INDICATIONS AND USAGE

Toviaz is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

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.

PRECAUTIONS

General

Bladder Outlet Obstruction

Toviaz should be administered with caution to patients with clinically significant bladder outlet obstruction because of the risk of urinary retention (see CONTRAINDICATIONS).

Decreased Gastrointestinal Motility

Toviaz, like other antimuscarinic drugs, should be used with caution in patients with decreased gastrointestinal motility, such as those with severe constipation.

Controlled Narrow-Angle Glaucoma

Toviaz should be used with caution in patients being treated for narrow-angle glaucoma, and only where the potential benefits outweigh the risks (see CONTRAINDICATIONS).

Reduced Hepatic Function

There are no dosing adjustments for patients with mild or moderate hepatic impairment. Toviaz has not been studied in patients with severe hepatic impairment and therefore is not recommended for use in this patient population (see CLINICAL PHARMACOLOGY, Pharmacokinetics in Special Populations and DOSAGE AND ADMINISTRATION).

Myasthenia Gravis

Toviaz should be used with caution in patients with myasthenia gravis, a disease characterized by decreased cholinergic activity at the neuromuscular junction.

Reduced Renal Function

There are no dosing adjustments for patients with mild or moderate renal insufficiency. Doses of Toviaz greater than 4 mg are not recommended in patients with severe renal insufficiency (see CLINICAL PHARMACOLOGY, Pharmacokinetics in Special Populations and DOSAGE AND ADMINISTRATION).

Concomitant Administration with CYP3A4 Inhibitors

Doses of Toviaz greater than 4 mg are not recommended in patients taking a potent CYP3A4 inhibitor (e.g. ketoconazole, itraconazole, clarithromycin).

In patients taking weak or moderate CYP3A4 inhibitors (e.g. erythromycin), careful assessment of tolerability at the 4 mg daily dose is advised prior to increasing the daily dose to 8 mg. While this specific interaction potential was not examined by clinical study, some pharmacokinetic interaction is expected, albeit less than that observed with potent CYP3A4 inhibitors (see CLINICAL PHARMACOLOGY, Drug-Drug Interactions and DOSAGE AND ADMINISTRATION).

Information for Patients

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 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.

Drug Interactions

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. Also see PRECAUTIONS, Concomitant Administration with CYP3A4 Inhibitors.

Drug-Laboratory Test Interactions

Interactions between Toviaz and laboratory tests have not been studied.

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) correspond to 11- to 19-fold (females) and 4- to 9-fold (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-fold (females) and 3- to 14-fold (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-fold higher in mice than in humans at the MRHD, whereas based on peak plasma concentrations, the exposure in mice was 5- to 9-fold higher. The Lowest-Observed-Effect Level (LOEL) for maternal toxicity was 45 mg/kg/day.

Pregnancy

Pregnancy Category C

Reproduction studies have been performed in mice and rabbits. No dose-related teratogenicity was observed at oral doses up to 75 mg/kg/day in mice (6 to 27 times the expected exposure at the MRHD based on AUC and greater than 77 times the expected C_{max}) and up to 27 mg/kg/day in rabbits (3- to 11- fold by AUC and 19- to 62– fold by C_{max}) or at subcutaneous doses up to 4.5 mg/kg/day in rabbits (9- to 11- fold by AUC and 43 to 56-fold by C_{max}). In mice treated orally with 75 mg/kg/day (6- to 27-times the expected exposure at the MRHD based on AUC and greater than 77-times the expected C_{max}), increased resorptions and decreased live fetuses were observed. One fetus with cleft palate was observed at each dose (15, 45 and 75 mg/kg/day), at an incidence within the background historical range. In rabbits treated orally with 27 mg/kg/day (3 to 11- fold by AUC and 19 to 62- fold by C_{max}), incompletely ossified sternebrae (retardation of bone development) were observed in fetuses. In rabbits treated by subcutaneous (sc) administration with 4.5 mg/kg/day (9 to 11- fold by AUC and 43 to 53- fold by C_{max}), maternal toxicity and incompletely ossified sternebrae were observed in fetuses (at an incidence within the background historical range). At 1.5 mg/kg/day s.c., (3-fold by AUC and 11 to 13- fold by C_{max}), 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 F_1 dams or on the F_2 offspring.

There are no adequate and well-controlled studies using Toviaz in pregnant women. Therefore, Toviaz should be used during pregnancy only if the potential benefit outweighs the potential risk to the fetus.

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.

Pediatric Use

The safety and effectiveness of Toviaz in pediatric patients have not been established.

Geriatric Use

Of 1567 patients who received Toviaz 4mg/day or 8mg/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 antimuscarinic adverse events, including dry mouth, constipation, dyspepsia, increase in residual urine, dizziness (at 8mg only) and urinary tract infection, was higher in patients 75 years of age and older as compared to younger patients. (see CLINICAL PHARMACOLOGY, Pharmacokinetics in Special Populations, and CLINICAL STUDIES and ADVERSE REACTIONS).

ADVERSE REACTIONS

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 8 or 12 weeks. Approximately 80% of these patients had >10 weeks exposure to Toviaz in these trials.

A total of 1964 patients participated in two 12-week, Phase 3 efficacy and safety studies and subsequent open-label extension studies. In these 2 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, gastroenteritis, 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 (35%) and in those taking 4 mg/day (19%), 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.

Table 3 lists adverse events, regardless of causality, that were reported in the combined Phase 3, 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.

Table 3 Adverse events with an incidence exceeding the placebo rate and reported by ≥1% of patients from double-blind, placebo-controlled Phase 3 trials of 12 weeks treatment duration

System organ class/Preferred term	Placebo N=554 %	Toviaz 4mg/day N=554 %	Toviaz 8mg/day N=566 %
Gastrointestinal disorders			
Dry mouth	7.0	18.8	34.6
Constipation	2.0	4.2	6.0
Dyspepsia	0.5	1.6	2.3
Nausea	1.3	0.7	1.9
Abdominal pain upper	0.5	1.1	0.5
Infections			
Urinary tract infection	3.1	3.2	4.2
Upper respiratory tract infection	2.2	2.5	1.8
Eye disorders			
Dry eyes	0	1.4	3.7
Renal and urinary disorders			
Dysuria	0.7	1.3	1.6
Urinary retention	0.2	1.1	1.4
Respiratory disorders			
Cough	0.5	1.6	0.9
Dry Throat	0.4	0.9	2.3
General disorders			
Edema peripheral	0.7	0.7	1.2
Musculoskeletal disorders			
Back pain	0.4	2.0	0.9
Psychiatric disorders			
Insomnia	0.5	1.3	0.4
Investigations			
ALT increased	0.9	0.5	1.2
GGT increased	0.4	0.4	1.2
Skin disorders			
Rash	0.5	0.7	1.1

ALT=alanine aminotransferase, GGT=gamma glutamyltransferase

Patients also received Toviaz for up to three years in open-label extension phases of one Phase 2 and two Phase 3 controlled trials. In all open label trials combined, 857, 701, 529, and 105 patients received Toviaz for at least 6 months, 1 year, 2 years, and 3 years respectively. The adverse events observed during long-term, open-label studies were similar to those observed in the 12-week, placebo-controlled studies, and included dry mouth, constipation, dry eyes, dyspepsia and abdominal pain. Similar to the controlled studies, most adverse events of dry mouth and constipation were mild to moderate in intensity. Serious adverse events, judged to be at least possibly related to study medication by the investigator, and reported more than once during the open-label treatment period of up to 3 years included urinary retention (3 cases), diverticulitis (3 cases), constipation (2 cases), irritable bowel syndrome (2 cases), and electrocardiogram QT corrected interval prolongation (2 cases).

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

The recommended starting dose of Toviaz is 4 mg once daily. Based upon individual response and tolerability, the dose may be increased to 8 mg once daily.

The daily dose of Toviaz should not exceed 4 mg in the following populations:

- Patients with severe renal insufficiency (CL_{CR} <30 mL/min).
- Patients taking potent CYP3A4 inhibitors, such as ketoconazole, itraconazole and clarithromycin.

Toviaz is not recommended for use in patients with severe hepatic impairment (see CLINICAL PHARMACOLOGY, Pharmacokinetics in Special Populations and PRECAUTIONS).

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.

HOW SUPPLIED

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
Bottles of 90	NDC 0069-0242-68
Unit Dose Package of 100	NDC 0069-0242-41

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
Bottles of 90	NDC 0069-0244-68
Unit Dose Package of 100	NDC 0069-0244-41

Storage

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.

Manufactured by:
SCHWARZ PHARMA PRODUKTIONS-GmbH
08056 Zwickau, Germany

Distributed by
Pfizer Labs
Division of Pfizer Inc, NY, NY 10017

LAB-0381-3.0
Revised November 2008

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.

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?

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?

- Use caution in driving, operating machinery, or doing other dangerous activities until you know how TOVIAZ affects you. Blurred vision 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, 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.

Manufactured by:
SCHWARZ PHARMA PRODUKTIONS-GmbH
08056 Zwickau, Germany

Distributed by
Pfizer Labs
Division of Pfizer Inc, NY, NY 10017

LAB-0382-3.0
Revised November 2008

Get the Full Picture in OAB Care

TOVIAZ—The Pill

- Rapidly and extensively converted to its active metabolite, 5-HMT, which is also the active metabolite of tolterodine[6]
- The flexibility of 2 doses (4 mg and 8 mg)
- Reductions in UUI seen as early as Week 2 and maintained through Week 12
- Fewer than 1% of patients discontinued due to dry mouth
- Long-term tolerability and safety supported by 3-year, open-label studies

YourWay™—The Plan

- Educates patients about managing their OAB symptoms
- Aims to help empower patients to take an active role in their OAB treatment

References: 1. Abrams P, Cardozo L, Fall M, et al. The standardisation of terminology of lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. *Neurourol Urodyn.* 2002;21:167-178. **2.** Milsom I, Abrams P, Cardozo L, Roberts RG, Thuroff J, Wein AJ. How widespread are the symptoms of an overactive bladder and how are they managed? a population-based prevalence study. *BJU Int.* 2001;87:760-766. **3.** Abrams P, Kelleher CJ, Kerr LA, Rogers RG. Overactive bladder significantly affects quality of life. *Am J Manag Care.* 2000;6(suppl 11):S580-S590. **4.** Nicolson P, Kopp Z, Chapple CR, Kelleher C. It's just the worry about not being able to control it! a qualitative study of living with overactive bladder. *Br J Health Psychol.* 2008;13:343-359. **5.** Coyne KS, Margolis MK, Jumadilova Z, Bavendam T, Mueller E, Rogers R. Overactive bladder and women's sexual health: what is the impact? *J Sex Med.* 2007;4:656-666. **6.** Detrol LA [package insert]. New York, NY: Pfizer Inc; March 2008. **7.** Data on file (CTD Figure 3.2.P.2.1.2-2). Pfizer Inc, New York, NY. **8.** Data on file (SP583 CSR Table 13.2.1.1.1). Pfizer Inc, New York, NY. **9.** Data on file (SCS 010). Pfizer Inc, New York, NY. **10.** Data on file (SCS 200). Pfizer Inc, New York, NY. **11.** Chapple C, Van Kerrebroeck P, Tubaro A, et al. Clinical efficacy, safety, and tolerability of once-daily fesoterodine in subjects with overactive bladder. *Eur Urol.* 2007;52:1204-1212. **12.** Nitti VW, Dmochowski R, Sand PK, et al. Efficacy, safety and tolerability of fesoterodine for overactive bladder syndrome. *J Urol.* 2007;178:2488-2494. **13.** Data on file (SP583 CSR Table 13.1.1.1.1). Pfizer Inc, New York, NY. **14.** PhRMA Web Synopses (CTR identifiers NCT00220376, Protocol A0221042). www.clinicalstudyresults.org. **15.** Data on file (SP738/739 SCS334 Table extent__vos_t.). Pfizer Inc, New York, NY. **16.** Data on file (Fesoterodine Summary of Clinical Safety, January 2006, Table 18.5). Pfizer Inc, New York, NY. **17.** Data on file. (SP583 and SP584 CSR Table 17.6.1). Pfizer Inc, New York, NY. **18.** Ginsberg DA, Phillips SF, Wallace J, Josephson KL. Evaluating and managing constipation in the elderly. *Urol Nurs.* 2007;27:191-212. **19.** Ouslander JG. Management of overactive bladder. *N Engl J Med.* 2004;350:786-799. **20.** Sussman DO. Overactive bladder: treatment options in primary care medicine. *J Am Osteopath Assoc.* 2007;107:379-385. **21.** Schaffer J. Urinary frequency, urgency, urge incontinence, and nocturia. In: Weber AM, Brubaker L, Schaffer J, Toglia MR, eds. *Office Urogynecology: Practical Pathways in Obstetrics and Gynecology.* New York, NY: McGraw-Hill; 2004:35-56. **22.** Herschorn S, Becker D, Miller E, Thompson M, Forte L. Impact of a health education intervention in overactive bladder patients. *Can J Urol.* 2004;11:2430-2437. **23.** Hashim H, Abrams P. How should patients with an overactive bladder manipulate their fluid intake? *BJU Int.* 2008;102:62-66. **24.** Burgio KL, Kraus SR, Menefee S, et al. Behavioral therapy to enable women with urge incontinence to discontinue drug treatment: a randomized trial. *Ann Intern Med.* 2008;149:161-169. **25.** MacStravic S. Optimising the patient's role: an essential component in disease management. *Dis Manage Health Outcomes.* 1999;6:1-7. **26.** Wyman JF, Fantl JA. Bladder training in ambulatory care management of urinary incontinence. *Urol Nurs.* 1991;11:11-17. **27.** Mattiasson A, Blaakaer J, Hoye K. Simplified bladder training augments the effectiveness of tolterodine in patients with an overactive bladder. *BJU Int.* 2003; 91:54-60. **28.** Fantl JA, Wyman JF, McClish DK, et al. Efficacy of bladder training in older women with urinary incontinence. *JAMA.* 1991;265:609-613. **29.** Hines SH. Adherence to a behavioral program to prevent incontinence. *West J Nurs Res.* 2007;29:36-56. **30.** Burgio KL, Locher JL, Goode PS, et al. Behavioral vs drug treatment for urge urinary incontinence in older women. *JAMA.* 1998;280:1995-2000. **31.** Nygaard IE, Kreder KJ, Lepic MM, Fountain KA, Rhomberg AT. Efficacy of pelvic floor muscle exercises in women with stress, urge, and mixed urinary incontinence. *Am J Obstet Gynecol.* 1996; 174:120-125. **32.** Subak LL, Whitcomb E, Shen H, Saxton J, Vittinghoff E, Brown JS. Weight loss: a novel and effective treatment for urinary incontinence. *J Urol.* 2005;174:190-195. **33.** Dallosso HM, McGrother CW, Matthews RJ, Donaldson MMK. The association of diet and other lifestyle factors with overactive bladder and stress incontinence: a longitudinal study in women. *BJU Int.* 2003;92:69-77.

TOVIAZ is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

The most frequently reported adverse events (≥4%) 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%).

Toviaz™
fesoterodine fumarate
extended release tablets 4mg and 8mg

Please see full prescribing and patient information on last pages.