HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use TOVIAZ safely and effectively. See full prescribing information for TOVIAZ.

TOVIAZ® (fesoterodine fumarate) extended-release tablets, for oral use
Initial U.S. Approval: 2008

----------RECENT MAJOR CHANGES----------

Indications and Usage (1.1, 1.2)	xx/2021
Dosage and Administration (2.1, 2.2, 2.3, 2.4, 2.5, 2.6)	xx/2021
Contraindictions (4)	xx/2021
Warnings and Precautions (5.1, 5.2, 5.3, 5.4, 5.6)	xx/2021

----------INDICATIONS AND USAGE----------

Toviaz is indicated for the treatment of:

- Overactive bladder (OAB) in adults with symptoms of urge urinary incontinence, urgency, and frequency. (1.1)
- Neurogenic detrusor overactivity (NDO) in pediatric patients 6 years of age and older and weighing greater than 25 kg. (1.2)

----------DOSAGE AND ADMINISTRATION----------

- OAB in Adults: The recommended starting dosage is 4 mg orally once daily. Based upon individual response and tolerability, increase to the maximum dosage of 8 mg once daily. (2.1)
- NDO in Pediatric Patients 6 Years and Older:
  - Pediatric Patients Weighing Greater than 25 kg and up to 35 kg: The recommended dosage is 4 mg orally once daily. If needed, dosage may be increased to 8 mg orally once daily. (2.2)
  - Pediatric Patients Weighing Greater than 35 kg: The recommended starting dosage is 4 mg orally once daily. After one week, increase to 8 mg orally once daily. (2.2)
- Adult or Pediatric Patients with Renal or Hepatic Impairment: Refer to the full prescribing information for recommended dosage. (2.3, 2.4)
- Dosage Modifications Due to Strong CYP3A4 Inhibitors: Refer to the full prescribing information for recommended dosage. (2.5)
- Administration: Swallow whole with liquid. Do not chew, divide, or crush. Take with or without food. (2.6)

----------DOSAGE FORMS AND STRENGTHS----------

Extended-release tablets: 4 mg and 8 mg (3)

----------CONTRAINDICATIONS----------

- Known or suspected hypersensitivity to Toviaz or any of its ingredients or to tolterodine tartrate tablets or tolterodine tartrate extended-release capsules. (4)
- Urinary retention (4)
- Gastric retention (4)
- Uncontrolled narrow-angle glaucoma. (4)

----------WARNINGS AND PRECAUTIONS----------

- Angioedema: Promptly discontinue Toviaz and provide appropriate therapy. (5.1)
- Urinary Retention: Toviaz is not recommended in patients with clinically significant bladder outlet obstruction because of the risk of urinary retention. (5.2)
- Decreased Gastrointestinal Motility: Toviaz is not recommended for use in patients with decreased gastrointestinal motility, such as those with severe constipation. (5.3)
- Worsening of Narrow Angle Glaucoma: Use Toviaz with caution in patients being treated for narrow-angle glaucoma. (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)
- Worsening of Myasthenia Gravis Symptoms: Use Toviaz with caution in patients with myasthenia gravis. (5.6)

----------ADVERSE REACTIONS----------

- Most frequently reported adverse events with Toviaz in adult patients with OAB (≥4%) 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%). (6.1)
- Most frequently reported adverse reactions with Toviaz in pediatric patients (≥2%) with NDO were: diarrhea, urinary tract infection (UTI), dry mouth, constipation, abdominal pain, nausea, weight increased, and headache. (6.1)

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.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 06/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Adult Overactive Bladder

Toviaz is indicated for the treatment of overactive bladder (OAB) in adults with symptoms of urge urinary incontinence, urgency, and frequency.

1.2 Pediatric Neurogenic Detrusor Overactivity

Toviaz is indicated for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients 6 years of age and older with a body weight greater than 25 kg.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage for Adult Patients with OAB

The recommended starting dosage of Toviaz in adults is 4 mg orally once daily. Based upon individual response and tolerability, increase to the maximum dosage of Toviaz 8 mg once daily. For administration instructions, *see Dosage and Administration (2.6).*

2.2 Recommended Dosage for Pediatric Patients Aged 6 Years and Older with NDO

Pediatric Patients Weighing Greater than 25 kg and up to 35 kg
The recommended dosage of Toviaz is 4 mg orally once daily. If needed, dosage may be increased to Toviaz 8 mg orally once daily. For administration instructions, *see Dosage and Administration (2.6).*

Pediatric Patients Weighing Greater than 35 kg
The recommended starting dosage of Toviaz is 4 mg orally once daily. After one week, increase to Toviaz 8 mg orally once daily. For administration instructions, *see Dosage and Administration (2.6).*

2.3 Recommended Dosage in Adult Patients with Renal Impairment

The recommended dosage of Toviaz in adult patients with renal impairment is described in Table 1 *[see Use in Specific Populations (8.6)]*. For administration instructions, *see Dosage and Administration (2.6).*

Table 1: Toviaz Recommended Dose in Adult Patients with Renal Impairment (Administered Orally Once Daily)

Estimated Creatinine Clearance[1]	Recommended Dose
CLcr 30 to 89 mL/min	8 mg
CLcr 15 to 29 mL/min	4 mg
CLcr <15 mL/min	4 mg

[1] Calculate CLcr using the Cockcroft-Gault formula

2.4 Recommended Dosage in Pediatric Patients with Renal Impairment

Pediatric Patients Weighing Greater than 25 kg and up to 35 kg

The recommended dosage of Toviaz in pediatric patients with renal impairment weighing greater than 25 kg and up to 35 kg is described in Table 2 *[see Use in Specific Populations (8.6)]*. For administration instructions, *see Dosage and Administration (2.6).*

Table 2: Toviaz Recommended Dose in Pediatric Patients Aged 6 Years and Older Weighing Greater than 25 kg and up to 35 kg with Renal Impairment (Administered Orally Once Daily)

Estimated Glomerular Filtration Rate (GFR)[1]	Recommended Dose[2]
eGFR 30 to 89 mL/min/1.73m^2	4 mg
eGFR 15 to 29 mL/min/1.73m^2	Use is Not Recommended
eGFR <15 mL/min/1.73m^2 or requiring dialysis	Use is Not Recommended

[1] Estimate GFR using a validated GFR estimating equation for the pediatric age range of the approved indication.
[2] Dosing was derived assuming similar proportional effects of renal impairment in adults and pediatric patients 6 years and older.

Pediatric Patients weighing greater than 35 kg

The recommended dosage of Toviaz in pediatric patients with renal impairment weighing greater than 35 kg is described in Table 3 *[see Use in Specific Populations (8.6)]*. For administration instructions, *see Dosage and Administration (2.6).*

Table 3: Toviaz Recommended Dose in Pediatric Patients Aged 6 Years and Older Weighing Greater Than 35 kg with Renal Impairment (Administered Orally Once Daily)

Estimated GFR[1]	Recommended Dose[3]
eGFR 30 to 89 mL/min/1.73m^2	8 mg[2]
eGFR15 to 29 mL/min/1.73m^2	4 mg
eGFR <15 mL/min/1.73m^2 or requiring dialysis	Use is Not Recommended

[1] Estimate GFR using a validated GFR estimating equation for the pediatric age range of the approved indication.
[2] The recommended starting dosage of Toviaz is 4 mg orally once daily. After one week, increase to the recommended dosage of Toviaz 8 mg orally once daily.
[3] Dosing was derived assuming similar proportional effects of renal impairment in adults and pediatric patients 6 years and older.

2.5 Toviaz Dosage Modifications Due to Strong CYP3A4 Inhibitors

Adult Patients with OAB

The maximum recommended dosage is Toviaz 4 mg orally once daily in adult patients taking strong CYP3A4 inhibitors *[see Drug Interactions (7.2) and Clinical Pharmacology (12.3)]*. For administration instructions, *see Dosage and Administration (2.6).*

Pediatric Patients with NDO

Pediatric Patients Weighing Greater than 25 kg and up to 35 kg

The use of Toviaz in pediatric patients weighing greater than 25 kg and up to 35 kg and taking strong CYP3A4 inhibitors is not recommended *[see Drug Interactions (7.2) and Clinical Pharmacology (12.3]*. For administration instructions, *see Dosage and Administration (2.6).*

Pediatric Patients Weighing Greater than 35 kg
The maximum recommended dosage is Toviaz 4 mg orally once daily in pediatric patients weighing greater than 35 kg and taking strong CYP3A4 inhibitors *[see Drug Interactions (7.2) and Clinical Pharmacology (12.3)]*. For administration instructions, *see Dosage and Administration (2.6)*.

2.6 Administration Instructions

Swallow Toviaz whole with liquid. Do not chew, divide, or crush. Take with or without food *[see Clinical Pharmacology (12.3)]*.

3 DOSAGE FORMS AND STRENGTHS

Extended-release tablets:
- 4 mg, light blue, oval, biconvex, film-coated, and engraved with “FS” on one side
- 8 mg, blue, oval, biconvex, film-coated, and engraved with “FT” on one side

4 CONTRAINDICATIONS

Toviaz is contraindicated in patients with any of the following:
- known or suspected hypersensitivity to Toviaz or any of its ingredients, or to tolterodine tartrate tablets or tolterodine tartrate extended-release capsules *[see Clinical Pharmacology (12.1)]*. Reactions have included angioedema *[see Warnings and Precautions (5.1)]*.
- urinary retention *[see Warnings and Precautions (5.2)]*
- gastric retention *[see Warnings and Precautions (5.3)]*
- uncontrolled narrow-angle glaucoma *[see Warnings and Precautions (5.4)]*

5 WARNINGS AND PRECAUTIONS

5.1 Angioedema

Angioedema of the face, lips, tongue, and/or larynx has been reported with Toviaz. In some cases, angioedema occurred after the first dose; however, cases have been reported to occur hours after the first dose or after multiple doses. Angioedema associated with upper airway swelling may be life-threatening.

Toviaz is contraindicated in patients with a known or suspected hypersensitivity to Toviaz or any of its ingredients *[see Contraindications (4)]*. If involvement of the tongue, hypopharynx, or larynx occurs, Toviaz should be promptly discontinued and appropriate therapy and/or measures to ensure a patent airway should be promptly provided.

5.2 Urinary Retention in Adult Patients with Bladder Outlet Obstruction

The use of Toviaz, like other antimuscarinic drugs, in patients with clinically significant bladder outlet obstruction, including patients with urinary retention, may result in further urinary retention and kidney injury. The use of Toviaz is not recommended in patients with clinically significant bladder outlet obstruction, and is contraindicated in patients with urinary retention *[see Contraindications (4) and Adverse Reactions (6.1)]*.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.