TOVIAZ® Abbreviated Prescribing Information:

(See Toviaz Summary of Product characteristics for full Prescribing Information)

Presentation: Prolonged-release tablets containing fesoterodine fumarate. The 4mg is light blue, oval, engraved FS containing 3.1mg of fesoterodine. The 8mg is blue, oval, engraved FT containing 6.2mg of fesoterodine. **Indications**: Symptomatic treatment of urge incontinence and/or urinary frequency and/or urgency that may occur in adult patients with overactive bladder syndrome.

Dosage: Adults (including Elderly): 4mg once daily. The tablet should be taken whole with some liquid. The dose may be increased to max daily dose of 8mg once daily. The max dose in patients with severe renal impairment or moderate hepatic impairment is 4mg. Treatment should be re-valuated after 8 weeks. Children: Not recommended. Cautious dose increase recommended in patients with mild or moderate renal impairment or mild hepatic impairment. Max dose with patients using moderate CYP3A4 inhibitors with mild or moderate renal impairment or mild hepatic impairment is 4mg. Use should be avoided in patients with mild renal or hepatic impairment using potent CYP3A4 inhibitors, or patients with severe renal impairment or moderate hepatic impairment using moderate CYP3A4 inhibitors. In patients receiving concomitant potent CYP3A4 inhibitors the max. daily dose is 4mg.

Contraindications: Hypersensitivity to fesoterodine, soya, peanut or excipients, urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, myasthenia gravis, severe hepatic impairment (Child Pugh C), severe ulcerative colitis, toxic megacolon. Concomitant use of potent CYP3A4 inhibitors in patients with moderate or severe renal impairment, or patients with moderate hepatic impairment.

Warnings and Precautions: Use with caution in patients with significant bladder outflow obstruction at risk of urinary retention, gastrointestinal obstructive disorders(e.g. pyloric stenosis), gastro-oesophageal reflux, concurrent medicinal products that may cause or exacerbate oesophagitis, autonomic neuropathy, controlled narrow-angle glaucoma, decreased gastrointestinal motility. Toviaz should not be used in patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. Fesoterodine should be used with caution in patients with risk factors for QT-prolongation including: electrolyte disturbances, bradycardia and concomitant administration of drugs known to prolong QT-interval, relevant pre-existing cardiac diseases especially when taking potent CYP3A4 inhibitors. Concomitant treatment with potent CYP2D6 inhibitors may increase exposure, and the dose should be increased with caution especially in patients with hepatic or renal impairment. Patients with a combination of hepatic or renal impairment or concomitant administration of potent or moderate CYP3A4 inhibitors or potent CYP2D6 inhibitors are expected to have additional exposure increases and dose dependant side effects – dose increase to 8mg where possible should be preceded by an evaluation of response and tolerability. Organic reasons for urge, frequency or overactive bladder should be considered before treatment. If angioedema occurs with fesoterodine use, fesoterodine should be discontinued and appropriate therapy promptly provided.

Drug Interactions: Concomitant use of other antimuscarinics and medicinal products with anticholinergic properties or with strong inhibitors of CYP3A4, may lead to more pronounced therapeutic and side-effects. Induction of CYP3A4 may lead to subtherapeutic plasma levels. Concomitant use with CYP3A4 inducers is not recommended. Co-administration of Toviaz with potent CYP2D6 inhibitors may lead to

increased exposure and adverse events. A dose reduction to 4mg may be required. Fesoterodine may reduce the effect of products that stimulate the motility of the gastro-intestinal tract.
Pregnancy & Lactation: Not recommended. See Full Prescribing Information.
Side Effects: In clinical trials, the most commonly reported adverse reaction was dry mouth. Common reported events include dizziness, headache, dry eye, dry throat, abdominal pain, diarrhoea, dyspepsia, constipation, nausea, dysuria, insomnia. Other side-effects include uncommon; tachycardia, palpitations, somnolence, blurred vision, vertigo, urinary retention (including feeling of residual urine), ALT increased, GGT increased; rare angioedema, confusional state. Refer to SmPC for information on other side effects.
Driving and operating machinery: The ability to drive and use machines may be affected by blurred vision, dizziness and somnolence, see side effects.
Overdose: Treat with gastric lavage and give activated charcoal. Treat symptomatically.
Legal Category: POM. **Marketing authorisation holder:** Pfizer Ltd, Ramsgate Road, Sandwich, Kent, CT13 9NJ, UK. **Package quantities, Marketing Authorisation numbers and basic NHS price:** TOVIAZ 4mg, 28 prolonged-release tablets, EU/1/07/386/003 £25.78; TOVIAZ 8mg, 28 prolonged-release tablets, EU/1/07/386/008 £25.78. **Further information is available on request from:** Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK. Tel: +44 (0) 1304 616161 **Date of Preparation:** March 2012**.**
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Pfizer Medical Information on 01304 616161.