For use in India only

To be sold by retail on the prescription of an Urologist only.

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Fesoterodine Fumarate Extended Release Tablets 4 mg & 8 mg

FesoBig 4/8 फेसोबिग ४/८

PRESCRIBING INFORMATION

1. GENERIC NAME

Fesoterodine Fumarate Extended Release Tablets 4 mg
Fesoterodine Fumarate Extended Release Tablets 8 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fesoterodine Fumarate Extended Release Tablets 4 mg
Each extended release tablet contains
Fesoterodine Fumarate IP .....4 mg

Colours: Titanium Dioxide IP, FD&C Blue Indigo Carmine Aluminium Lake

Fesoterodine Fumarate Extended Release Tablets 8 mg
Each extended release tablet contains
Fesoterodine Fumarate IP .....8 mg

Colours: Titanium Dioxide IP, FD&C Blue Indigo Carmine Aluminium Lake,

3. DOSAGE FORM AND STRENGTH

Fesoterodine is available as 4 mg and 8 mg extended release tablets.

4. CLINICAL PARTICULARS

4.1. Indications

Fesoterodine is a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

4.2. Posology and Method of Administration

The recommended starting dose of Fesoterodine 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 Fesoterodine should not exceed 4 mg in the following populations:

- Patients with severe renal impairment (CLCR <30 mL/min).
- Patients taking potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, and clarithromycin

Fesoterodine is not recommended for use in patients with severe hepatic impairment (Child-Pugh C).
Fesoterodine should be taken with liquid and swallowed whole. Fesoterodine can be administered with or without food, and should not be chewed, divided, or crushed.

4.3. Contraindications

Fesoterodine is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma, myasthenia gravis, severe hepatic impairment (Child Pugh C), concomitant use of potent CYP3A4 inhibitors in subjects with moderate to severe hepatic or renal impairment, severe ulcerative colitis and toxic megacolon.

Fesoterodine 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.

4.4. Special Warnings and Precautions for Use

Angioedema
Angioedema of the face, lips, tongue, and/or larynx has been reported with Fesoterodine. In some cases, angioedema occurred after the first dose. Angioedema associated with upper airway swelling may be life-threatening. If involvement of the tongue, hypopharynx, or larynx occurs, Fesoterodine should be promptly discontinued and appropriate therapy and/or measures to ensure a patent airway should be promptly provided.

Bladder Outlet Obstruction
Fesoterodine should be administered with caution to patients with clinically significant bladder outlet obstruction because of the risk of urinary retention.

Decreased Gastrointestinal Motility
Fesoterodine, 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
Fesoterodine should be used with caution in patients being treated for narrow-angle glaucoma, and only where the potential benefits outweigh the risks.

Central Nervous System Effects
Fesoterodine is associated with anticholinergic central nervous system (CNS) effects. A variety of CNS anticholinergic effects have been reported, including headache, dizziness, and somnolence.

Patients should be monitored for signs of anticholinergic CNS effects, particularly after beginning treatment or increasing the dose. Advise patients not to drive or operate heavy machinery until they know how Fesoterodine affects them. If a patient experiences anticholinergic CNS effects, dose reduction or drug discontinuation should be considered.

Hepatic Impairment
Fesoterodine has not been studied in patients with severe hepatic impairment and therefore is not recommended for use in this patient population.

Renal Impairment
Doses of Fesoterodine greater than 4 mg are not recommended in patients with severe renal impairment.

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

No dosing adjustments are recommended in the presence of moderate CYP3A4 inhibitors (e.g., erythromycin, fluconazole, diltiazem, verapamil and grapefruit juice).

While the effect of weak CYP3A4 inhibitors (e.g. cimetidine) was not examined by clinical study, some pharmacokinetic interaction is expected, albeit less than that observed with moderate CYP3A4 inhibitors.

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

Potent CYP3A4 inducers
The concomitant use of fesoterodine with a potent CYP3A4 inducer (i.e. carbamazepine, rifampicin, phenobarbital, phenytoin, St John's Wort) is not recommended.

QT prolongation
Fesoterodine should be used with caution in patients with risk for QT prolongation (e.g. hypokalaemia, bradycardia and concomitant administration of medicines known to prolong QT interval) and relevant pre-existing cardiac diseases (e.g. myocardial ischaemia, arrhythmia, congestive heart failure). This especially holds true when taking potent CYP3A4 inhibitors.

Lactose
Fesoterodine extended release tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5. Drug Interactions

Antimuscarinic Drugs
Coadministration of Fesoterodine 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.

CYP3A4 Inhibitors
Doses of Fesoterodine 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 Fesoterodine. Compared with CYP2D6 extensive metabolizers not taking ketoconazole, further increases in the exposure to 5-HMT were observed in population who were CYP2D6 poor metabolizers taking ketoconazole.

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 200 mg twice a day for 2 days, the average (90% confidence interval) increase in C_{max} and 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., erythromycin, 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.

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 Fesoterodine 8 mg. The terminal half-life of the active metabolite was not changed.

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.

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.

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.

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.

Paediatric population
Interaction studies have only been performed in adults.

Drug-Laboratory Test Interactions
Interactions between Fesoterodine and laboratory tests have not been studied.

4.6. Use in Special Populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy
There are no data with the use of Fesoterodine in pregnant women to inform a drug associated risk for birth defects or miscarriage. In animal reproduction studies, oral administration of Fesoterodine to pregnant mice and rabbits during organogenesis resulted in fetotoxicity at maternal exposures that were 6 and 3 times, respectively, the maximum recommended human dose (MRHD) of 8 mg/day based on AUC. The background risk of major birth defects and miscarriage for the indicated population are unknown. Fesoterodine is not recommended during pregnancy.

Lactation
There is no information on the presence of Fesoterodine in human milk, the effects on the breastfed child, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Fesoterodine and any potential adverse effects on the breastfed child from Fesoterodine or from the underlying maternal condition.

Fertility
No clinical trials have been conducted to assess the effect of fesoterodine on human fertility.
Findings in mice at exposures approximately 5 to 19 times those at the MRHD show an effect on female fertility, however, the clinical implications of these animal findings are not known. Women of child bearing potential should be made aware of the lack of human fertility data, and Fesoterodine should only be given after consideration of individual risks and benefits.

Pediatric Use
The pharmacokinetics of Fesoterodine has not been evaluated in pediatric patients. The safety and effectiveness of Fesoterodine in pediatric patients have not been established.

Geriatric Use
No dose adjustment is recommended for the elderly. The pharmacokinetics of Fesoterodine is not significantly influenced by age.

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 8 mg only) and urinary tract infection, was higher in patients 75 years of age and older as compared to younger patients.

Renal Impairment
Doses of Fesoterodine greater than 4 mg are not recommended in patients with severe renal impairment. No dose adjustment is recommended in patients with mild or moderate renal impairment.

Hepatic Impairment
Patients with severe hepatic impairment (Child-Pugh C) have not been studied; therefore, Fesoterodine is not recommended for use in these patients. No dose adjustment is recommended in patients with mild or moderate hepatic impairment.

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

Race
Available data indicate that there are no differences in the pharmacokinetics of Fesoterodine between Caucasian and Black healthy population following administration of Fesoterodine.

4.7. Effects on Ability to Drive and Use Machines

Fesoterodine has minor influence on the ability to drive and use machines. Caution should be exercised when driving or using machines due to possible occurrence of side effects such as blurred vision, dizziness, and somnolence.

4.8. Undesirable Effects

Tabulated list of adverse reactions
The adverse reactions are reported in this table with the following frequency convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

System organ class	Very common	Common	Uncommon	Rare
Infections and infestations			Urinary tract infection	
Psychiatric disorders		Insomnia		Confusional state
Nervous system disorders		Dizziness; Headache	Dysgeusia; Somnolence	
Eye disorders		Dry eye	Blurred vision	
Cardiac disorders			Tachycardia; Palpitations	
Respiratory, thoracic and mediastinal disorders		Dry throat	Pharyngolaryngeal pain; Cough; Nasal dryness	
Gastrointestinal disorders	Dry mouth	Abdominal pain; Diarrhoea; Dyspepsia; Constipation; Nausea	Abdominal discomfort; Flatulence, Gastroesophageal reflux	
Hepatobiliary disorders			ALT increased; GGT increased	
Skin and subcutaneous tissue disorders			Rash; Dry skin; Pruritus	Angioedema; Urticaria
Renal and urinary disorders		Dysuria	Urinary retention (including feeling of residual urine; micturition disorder); Urinaryhesitation	
General disorders and administration site conditions			Fatigue	

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. To report Suspected Adverse Reactions, contact MSN Laboratories Private Limited at pharmacovigilance@msnlabs.com or through company website www.msnlabs.com->Contact us->Medical Enquiry/ to report a side effect.

4.9. Overdose

Overdose with antimuscarinics, including fesoterodine can result in severe anticholinergic effects.
Treatment should be symptomatic and supportive. In the event of overdose, ECG monitoring is recommended; standard supportive measures for managing QT prolongation should be adopted. Fesoterodine has been safely administered in clinical studies at doses up to 28 mg/day.
In the event of fesoterodine overdose, treat with gastric lavage and give activated charcoal. Treat symptoms as follows:
- Severe central anticholinergic effects (e.g. hallucinations, severe excitation): treat with physostigmine
- Convulsions or pronounced excitation: treat with benzodiazepines
- Respiratory insufficiency: treat with artificial respiration
- Tachycardia: treat with beta-blockers
- Urinary retention: treat with catheterisation
- Mydriasis: treat with pilocarpine eye drops and/or place patient in dark room.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of action

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 and is also one of the active moieties of tolterodine tartrate tablets and tolterodine tartrate extended-release capsules.

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.

5.2 Pharmacodynamic Properties

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.

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.

Fesoterodine 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 *[Reference: Toviaz USFDA Label. Dated: Nov-2017].*

5.2 Pharmacokinetic Properties

Absorption
After oral administration, fesoterodine is well absorbed. Due to rapid and extensive hydrolysis by nonspecific esterases to its active metabolite 5-hydroxymethyl tolterodine, 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.

Effect of Food: There is no clinically relevant effect of food on the pharmacokinetics of fesoterodine. In a study of the effects of food on the pharmacokinetics of fesoterodine in 16 healthy male volunteers, concomitant food intake increased the active metabolite of fesoterodine AUC by approximately 19% and C_{max} by 18%.

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 CYP2D6 Metabolism: A subset of individuals (approximately 7% of Caucasians and approximately 2% of African Americans) are poor metabolizers for CYP2D6. 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.

Specific Populations

Geriatric Patients: The pharmacokinetics of Fesoterodine was not significantly influenced by age.

Pediatric Patients: The pharmacokinetics of Fesoterodine has not been evaluated in pediatric patients.

Gender: The pharmacokinetics of Fesoterodine was not significantly influenced by gender.

Race: The pharmacokinetics of Fesoterodine were not significantly influenced by race.

Renal Impairment: In patients with mild or moderate renal impairment (CLCR 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 impairment (CLCR < 30 mL/min), C_{max} and AUC are increased 2.0-and 2.3-fold, respectively.

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. Subjects with severe hepatic impairment (Child-Pugh C) have not been studied *[Reference: Toviaz USFDA Label. Dated: Nov-2017].*

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 Fesoterodine 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 coadministration of ketoconazole 200 mg twice a day for 5 days. C_{max} and AUC were 4.5-and 5.7-fold higher, respectively, in CYP2D6 poor metabolizers and taking ketoconazole compared to people who were CYP2D6 extensive metabolizers and not taking ketoconazole.

There is no clinically relevant effect of moderate CYP3A4 inhibitors on the pharmacokinetics of fesoterodine.

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 Fesoterodine 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 studied. 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.

Oral Contraceptives: Fesoterodine increased the AUC and C_{max} of ethinyl estradiol by 1 – 3% and decreased the AUC and C_{max} of levonorgestrel by 11 – 13%.

Warfarin: There were no statistically significant changes in the measured pharmacodynamic parameters for anti-coagulant activity of a single dose of warfarin.

6. NONCLINICAL PROPERTIES

6.1 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) correspond 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 male reproductive function or fertility at doses up to 45 mg/kg/day in mice. At 45 mg/kg/day, a lower number of corpora lutea, implantation sites and viable fetuses was observed in female mice administered fesoterodine for 2 weeks prior to mating and continuing through day 7 of gestation. The maternal No-Observed-Effect Level (NOEL) and the NOEL for effects on reproduction and early embryonic development were both 15 mg/kg/day. At the NOEL, , the systemic exposure, based on AUC, 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 *[Reference: Toviaz USFDA Label. Dated: Nov-2017].*

7. PHARMACEUTICAL PARTICULARS

7.1 Incompatibilities

None

7.2 Packing Information

10's Blister Pack.

7.3 Storage and Handling Instructions

Store below 25°C.
Protect from moisture.

8. PATIENT COUNSELING INFORMATION

Advise the patient to read package insert.

Angioedema
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.

Antimuscarinic Effects
Patients should be informed that Fesoterodine, like other antimuscarinic agents, may produce clinically significant adverse effects related to antimuscarinic pharmacological activity including constipation and urinary retention. Fesoterodine, 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 Fesoterodine, like other antimuscarinic drugs, is used in a hot environment.

Alcohol
Patients should also be informed that alcohol may enhance the drowsiness caused by Fesoterodine, like other anticholinergic agents. Patients should read the patient leaflet before starting therapy with Fesoterodine.

9. DETAILS OF MANUFACTURER

MSN Laboratories Private Limited,
(Formulations Division), Plot No. 42,
Anrich Industrial Estate, Bollaram,
Sangareddy District - 502 325,
Telangana, INDIA.

B33352-00

10. DETAILS OF MANUFACTURING LICENCE NUMBER

Mfg. Lic. No.: 38/MD/AP/2007/F/CC

11. DATE OF REVISION

June 2023