HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use FLOMAX safely and effectively. See full prescribing information for FLOMAX.

FLOMAX® (tamsulosin hydrochloride, USP) capsules, for oral use

Initial U.S. Approval: 1997

INDICATIONS AND USAGE

• FLOMAX is an alpha, adrenoceptor antagonist indicated for treatment of the signs and symptoms of benign prostatic hyperplasia (1)

DOSAGE AND ADMINISTRATION

• 0.4 mg once daily taken approximately one-half hour following the same meal each day. FLOMAX capsules should not be crushed, chewed or opened. (2)

• Can be increased to 0.8 mg once daily for patients who fail to respond to the 0.4 mg dose after 2 to 4 weeks of dosing (2)

• If discontinued or interrupted for several days at either the 0.4 mg or 0.8 mg dose, therapy should start again with the 0.4 mg once-daily dose (2)

Dosage Forms and Strengths

Capsules: 0.4 mg (3)

Contraindications

Contraindicated in patients known to be hypersensitive to tamsulosin hydrochloride or any component of FLOMAX capsules (4, 6.2)

WARNINGS AND PRECAUTIONS

• Advise patients about the possibility of symptoms related to postural hypotension and to avoid situations where injury could result should syncope occur (5.1)

• Should not be used in combination with strong inhibitors of CYP3A4. Use with caution in combination with moderate inhibitors of CYP3A4 (e.g., erythromycin), in combination with strong (e.g., paroxetine) or moderate (e.g., terbinafine) inhibitors of CYP2D6, or in patients known to be CYP2D6 poor metabolizers, particularly at a dose higher than 0.4 mg (e.g., 0.8 mg). (5.2, 7.1, 12.3)

• Concomitant use of PDE5 inhibitors with tamsulosin can potentially cause symptomatic hypotension (5.2, 7.3, 12.3)

ADVERSE REACTIONS

The most common adverse events (≥2% of patients and at a higher incidence than placebo) with the 0.4 mg dose or 0.8 mg dose were headache, dizziness, rhinitis, infection, abnormally elevated alanine aminotransferase (AST), abnormally elevated aspartate aminotransferase (ALT), and diarrhea. Severe adverse reactions included asthenia, back pain, chest pain, cough increased, somnolence, nausea, sinusitis, insomnia, libido decreased, tooth disorder, and blurred vision (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact sanofi-aventis U.S. LLC at 1-800-633-1610 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

• FLOMAX capsules should be used with caution in combination with moderate inhibitors of CYP3A4 (e.g., erythromycin), in combination with strong (e.g., paroxetine) or moderate (e.g., terbinafine) inhibitors of CYP2D6, or in patients known to be CYP2D6 poor metabolizers, particularly at a dose higher than 0.4 mg (e.g., 0.8 mg). (5.2, 7.1, 12.3)

• Concomitant use of PDE5 inhibitors with tamsulosin can potentially cause symptomatic hypotension (5.2, 7.3, 12.3)

USE IN SPECIFIC POPULATIONS

• Pediatric Use: Not indicated for use in pediatric populations (8.4, 12.3)

• Geriatric Use: No overall differences in efficacy or safety vs younger patients, but greater sensitivity of some older adults cannot be ruled out (8.5, 12.3)

• Renal Impairment: Has not been studied in patients with end-stage renal disease (8.6, 12.3)

• Hepatic Impairment: Has not been studied in patients with severe hepatic impairment (8.7, 12.3)

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

Revised: 01/2019

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

FLOMAX (tamsulosin hydrochloride, USP) capsules are indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) [see Clinical Studies (14)]. FLOMAX capsules are not indicated for the treatment of hypertension.

2 DOSAGE AND ADMINISTRATION

FLOMAX capsules 0.4 mg once daily is recommended as the dose for the treatment of the signs and symptoms of BPH. It should be administered approximately one-half hour following the same meal each day. FLOMAX capsules should not be crushed, chewed, or opened.

For those patients who fail to respond to the 0.4 mg dose after 2 to 4 weeks of dosing, the dose of FLOMAX capsules can be increased to 0.8 mg once daily. FLOMAX capsules 0.4 mg should not be used in combination with strong inhibitors of CYP3A4 (e.g., ketoconazole) [see Warnings and Precautions (5.2)].

If FLOMAX capsules administration is discontinued or interrupted for several days at either the 0.4 mg or 0.8 mg dose, therapy should be started again with the 0.4 mg once-daily dose.

3 DOSAGE FORMS AND STRENGTHS

Capsule: 0.4 mg, olive green and orange hard gelatin, imprinted on one side with Flomax 0.4 mg and on the other side with BI 58.

4 CONTRAINDICATIONS

FLOMAX capsules are contraindicated in patients known to be hypersensitive to tamsulosin hydrochloride or any component of FLOMAX capsules. Reactions have included skin rash, urticaria, pruritus, angioedema, and respiratory symptoms [see Adverse Reactions (6.2)].

5 WARNINGS AND PRECAUTIONS

5.1 Orthostasis

The signs and symptoms of orthostasis (postural hypotension, dizziness, and vertigo) were detected more frequently in FLOMAX capsule-treated patients than in placebo recipients. As with other alpha adrenergic blocking agents there is a potential risk of syncope [see
5.2 Drug Interactions
Tamsulosin is extensively metabolized, mainly by CYP3A4 and CYP2D6. FLOMAX capsules 0.4 mg should not be used in combination with strong inhibitors of CYP3A4 (e.g., ketoconazole) [see Drug Interactions (7.1) and Clinical Pharmacology (12.3)]. FLOMAX capsules should be used with caution in combination with moderate inhibitors of CYP3A4 (e.g., erythromycin), in combination with strong (e.g., paroxetine) or moderate (e.g., terbinafine) inhibitors of CYP2D6, in patients known to be CYP2D6 poor metabolizers particularly at a dose higher than 0.4 mg (e.g., 0.8 mg) [see Drug Interactions (7.1) and Clinical Pharmacology (12.3)].

FLOMAX capsules should be used with caution in combination with cimetidine, particularly at a dose higher than 0.4 mg (e.g., 0.8 mg) [see Drug Interactions (7.1) and Clinical Pharmacology (12.3)]. FLOMAX capsules should not be used in combination with other alpha adrenergic blocking agents [see Drug Interactions (7.2) and Clinical Pharmacology (12.3)]. Caution is advised when alpha adrenergic blocking agents including FLOMAX are coadministered with CYP3A4 substrates, as tamsulosin is a CYP3A4 substrate. If a patient is started on a CYP3A4 substrate and either FLOMAX capsules 0.4 mg or 0.8 mg and at an incidence numerically higher than that in the placebo group during two 13-week U.S. trials (US92-03A and US93-01) of FLOMAX capsules 0.4 mg once daily and 4% (9 of 253) in the 0.8 mg group, and by 0.6% (75 of 502) in the 0.4 mg group, 17% of patients (84 of 492) in the 0.8 mg group, and 10% of patients (50 of 493) in the placebo group. Vertigo was reported by 0.6% of patients (31 of 498) in the 0.4 mg group, 1% of patients (5 of 492) in the 0.8 mg group, and by 0.6% of patients (3 of 502) in the 0.4 mg group, 1% of patients (5 of 492) in the 0.8 mg group, and by 0.6% of patients (3 of 493) in the placebo group.

Multiple testing for orthostatic hypotension was conducted in a number of studies. Such a test was considered positive if it met one or more of the following criteria: (1) a decrease in systolic blood pressure of ≥20 mmHg upon standing from the supine position during the orthostatic test; (2) a decrease in diastolic blood pressure ≥10 mmHg upon standing, with the standing diastolic blood pressure <85 mmHg during the orthostatic test; (3) an increase in pulse rate of ≥20 bpm upon standing with a standing pulse rate ≥100 bpm during the orthostatic test; and (4) the presence of clinical symptoms (faintness, lightheadedness/lightheaded, dizziness, spinning sensation, vertigo, or postural hypotension) upon standing during the orthostatic test.

Following the first dose of double-blind medication in Study 1, a positive orthostatic test result at 4 hours post dose was observed in 7% of patients (37 of 498) who received FLOMAX capsules 0.4 mg once daily and in 3% of the patients (8 of 253) who received placebo. At 8 hours post dose, a positive orthostatic test result was observed for 6% of the patients (31 of 498) who received FLOMAX capsules 0.4 mg once daily and 4% (250) who received placebo (Note: patients in the 0.8 mg group received 0.4 mg once daily for the first week of Study 1).

In Studies 1 and 2, at least one positive orthostatic test result was observed during the course of these studies for 81 of the 502 patients (16%) in the FLOMAX capsules 0.4 mg once-daily group, 92 of the 491 patients (19%) in the FLOMAX capsules 0.8 mg once-daily group, and 54 of the 493 patients (11%) in the placebo group.

Table 1: Treatment-Emergent Adverse Events Occurring in ≥2% of FLOMAX Capsules or Placebo Patients in Two U.S. Short-Term Placebo-Controlled Clinical Studies

<table>
<thead>
<tr>
<th>BODY SYSTEM/ADVERSE EVENT</th>
<th>FLOMAX CAPSULES GROUPS</th>
<th>PLACEBO</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.4 mg 502</td>
<td>0.8 mg 492</td>
<td>n=493</td>
</tr>
</tbody>
</table>

NERVOUS SYSTEM
- Dizziness: 75 (14.9%) 84 (17.1%) 50 (10.1%)
- Somnolence: 15 (3.0%) 21 (4.3%) 8 (1.6%)
- Insomnia: 12 (2.4%) 7 (1.4%) 3 (0.6%)
- Libido decreased: 5 (1.0%) 10 (2.0%) 6 (1.2%)

RESPIRATORY SYSTEM
- Rhinitis*: 66 (13.1%) 88 (17.9%) 41 (8.3%)
- Pharyngitis: 29 (5.8%) 25 (5.1%) 23 (4.7%)
- Cough increased: 17 (3.4%) 22 (4.5%) 12 (2.4%)
- Sinusitis: 11 (2.2%) 18 (3.7%) 8 (1.6%)

DENTAL SYSTEM
- Tooth disorder: 6 (1.2%) 10 (2.0%) 7 (1.4%)

URINOGENITAL SYSTEM
- Abnormal ejaculation: 42 (8.4%) 89 (18.1%) 1 (0.2%)

SPECIAL SENSES
- Blurred vision: 1 (0.2%) 10 (2.0%) 2 (0.4%)

*A treatment-emergent adverse event was defined as any event satisfying one of the following criteria:
- The adverse event occurred for the first time after initial dosing with double-blind study medication;
- The adverse event was present prior to or at the time of initial dosing with double-blind study medication and subsequently increased in severity during double-blind treatment; or
- The adverse event was present prior to or at the time of initial dosing with double-blind study medication, disappeared completely, and then reappeared during double-blind treatment.

Coding preferred terms also include cold, common cold, head cold, flu, and flu-like symptoms.

**Coding preferred terms also include nasal congestion, stuffy nose, runny nose, sinus congestion, and hay fever.

Signs and Symptoms of Osteoarthritis
In the two U.S. studies, symptomatic postural hypotension was reported by 0.2% of patients (1 of 502) in the 0.4 mg group, 0.4% of patients (2 of 492) in the 0.8 mg group, and by no patients in the placebo group. Syncope was reported by 0.2% of patients (1 of 502) in the 0.4 mg group, 0.4% of patients (2 of 492) in the 0.8 mg group, and 0.6% of patients (3 of 493) in the placebo group. Dizziness was reported by 15% of patients (75 of 502) in the 0.4 mg group, 17% of patients (84 of 492) in the 0.8 mg group, and 10% of patients (50 of 493) in the placebo group. Vertigo was reported by 0.6% of patients (3 of 502) in the 0.4 mg group, 1% of patients (5 of 492) in the 0.8 mg group, and by 0.6% of patients (3 of 493) in the placebo group.

Multiple testing for orthostatic hypotension was conducted in a number of studies. Such a test was considered positive if it met one or more of the following criteria: (1) a decrease in systolic blood pressure of ≥20 mmHg upon standing from the supine position during the orthostatic test; (2) a decrease in diastolic blood pressure ≥10 mmHg upon standing, with the standing diastolic blood pressure <85 mmHg during the orthostatic test; (3) an increase in pulse rate of ≥20 bpm upon standing with a standing pulse rate ≥100 bpm during the orthostatic test; and (4) the presence of clinical symptoms (faintness, lightheadedness/lightheaded, dizziness, spinning sensation, vertigo, or postural hypotension) upon standing during the orthostatic test.

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In Studies 1 and 2, at least one positive orthostatic test result was observed during the course of these studies for 81 of the 502 patients (16%) in the FLOMAX capsules 0.4 mg once-daily group, 92 of the 491 patients (19%) in the FLOMAX capsules 0.8 mg once-daily group, and 54 of the 493 patients (11%) in the placebo group.

Table 1: Treatment-Emergent Adverse Events Occurring in ≥2% of FLOMAX Capsules or Placebo Patients in Two U.S. Short-Term Placebo-Controlled Clinical Studies (continued)
Because orthostasis was detected more frequently in FLOMAX capsule-treated patients than in placebo recipients, there is a potential risk of syncope [see Warnings and Precautions (5.1)].

11 DESCRIPTION

Tamsulosin hydrochloride is (-)-5-[2-[(2-ethoxyphenoxy)ethyl]amino]propyl]-2-fluorophenylhydantoin. Tamsulosin hydrochloride is a white crystalline powder that melts with decomposition at approximately 230°C. It is sparingly soluble in water and methyl alcohol, slightly soluble in glacial acetic acid, practically insoluble in ether.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Tamsulosin hydrochloride is a competitive inhibitor of alpha1A-adrenoceptors. In vitro, the tamsulosin hydrochloride molecule is selectively bound to alpha1A-adrenoceptors, and in vivo, its primary activity is associated with alpha1A-adrenoceptors in the prostate and bladder neck. Tamsulosin hydrochloride is not a full agonist and shows a weak intrinsic activity at the alpha1A-adrenoceptors.

12.2 Pharmacodynamics

The selectivity of tamsulosin hydrochloride is reflected in its pharmacodynamic properties. Tamsulosin hydrochloride significantly reduces the PVR without altering the detrusor pressure. In addition, tamsulosin hydrochloride significantly reduces the prevalence of acute urinary retention associated with BPH.

12.3 Pharmacokinetics

Tamsulosin hydrochloride is well absorbed after oral administration. The absolute bioavailability of tamsulosin hydrochloride is approximately 100% when administered orally. The peak plasma concentrations of tamsulosin are reached approximately 5 hours after oral administration. The mean steady-state plasma concentration of tamsulosin in patients with normal renal function is 1.3 ng/mL. The mean terminal half-life of tamsulosin is 13 hours. Tamsulosin is extensively metabolized by the liver. The major metabolites of tamsulosin are 4-hydroxy-tamsulosin, 4,6-dihydroxy-tamsulosin, and 4-carboxy-tamsulosin. These metabolites are excreted in the urine.

12.4 Special Populations

12.4.1 Effect of Age

There were no substantial differences in tamsulosin exposure between elderly patients and younger patients. There is no evidence that age affects the disposition of tamsulosin.

12.4.2 Effect of Gender

The elimination of tamsulosin is similar in male and female patients.

12.4.3 Effect of Renal Function

The elimination of tamsulosin in patients with renal impairment is similar to that in patients with normal renal function. No dosage adjustment is required in patients with moderate or severe renal impairment.

12.4.4 Effect of Hepatic Function

There is no information available on the effect of hepatic function on the pharmacokinetics of tamsulosin. There is no need for dosage adjustment in patients with mild to moderate hepatic impairment.

12.4.5 Effect of Cardiovascular Disease

There is no information available on the effect of cardiovascular disease on the pharmacokinetics of tamsulosin. There is no need for dosage adjustment in patients with cardiovascular disease.

12.4.6 Effect of Smoking

There is no information available on the effect of smoking on the pharmacokinetics of tamsulosin. There is no need for dosage adjustment in smokers.

12.4.7 Effect of CYP3A4 and CYP2D6 Enzyme Activity

Tamsulosin is a substrate of CYP3A4 and CYP2D6. The effects of concomitant administration of a moderate CYP3A4 inhibitor (e.g., erythromycin) on the pharmacokinetics of FLOMAX have not been evaluated [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)].

Concomitant treatment with ketoconazole (a strong inhibitor of CYP3A4) resulted in an increase in the Cmax and AUC of tamsulosin by a factor of 2.2 and 2.8, respectively [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)]. The effects of coadministration of a moderate CYP3A4 inhibitor (e.g., erythromycin) on the pharmacokinetics of FLOMAX have not been evaluated [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)].

Concomitant treatment with paroxetine (a strong inhibitor of CYP2D6) resulted in an increase in the Cmax and AUC of tamsulosin by a factor of 1.3 and 1.6, respectively [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)]. A similar increase in exposure is expected in CYP2D6 poor metabolizers (PM) as compared to extensive metabolizers (EM). Since CYP2D6 PMs cannot be readily identified and the potential for significant increase in tamsulosin exposure exists when FLOMAX 0.4 mg is coadministered with strong CYP3A4 inhibitors in CYP2D6 PMs, FLOMAX capsules 0.4 mg should not be used in combination with strong inhibitors of CYP3A4 (e.g., ketoconazole) [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)].

The effects of concomitant administration of a moderate CYP2D6 inhibitor (e.g., terbutaline) on the pharmacokinetics of FLOMAX have not been evaluated [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)].

The effects of coadministration of both a CYP3A4 and a CYP2D6 inhibitor with FLOMAX capsules have not been evaluated. However, there is a potential for significant increase in tamsulosin exposure when FLOMAX 0.4 mg is coadministered with a combination of both CYP3A4 and CYP2D6 inhibitors [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)].

Cimetidine treatment with cimetidine resulted in a significant decrease (26%) in the clearance of tamsulosin hydrochloride, which resulted in a moderate increase in tamsulosin hydrochloride AUC (44%) [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)].

7.2 Other Alpha Adrenergic Blocking Agents

The pharmacokinetic and pharmacodynamic interactions between FLOMAX capsules and other alpha adrenergic blocking agents have not been determined; however, interactions between FLOMAX capsules and other alpha adrenergic blocking agents may be expected [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)].

7.3 PD5 Inhibitors

Caution is advised when alpha adrenergic blocking agents including FLOMAX are coadministered with PD5 inhibitors. Alpha-adrenergic blockers and PD5 inhibitors are both vasodilators that can lower blood pressure. Concomitant use of these two drug classes can potentially cause symptomatic hypotension [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)].

7.4 Warfarin

A definitive drug-drug interaction study between tamsulosin hydrochloride and warfarin has not been performed. Therefore, patients should be monitored closely for changes in international normalized ratio (INR) and prothrombin time (PT). If necessary, vasopressors should be used to maintain blood pressure and normal rate of urine production. Supportive measures as appropriate for hypotension should be used, including the administration of intravenous fluids should be considered. If necessary, vasopressors should then be used and renal function should be monitored and supported as needed. Laboratory data indicate that tamsulosin hydrochloride is 94% to 99% protein bound; therefore, dialysis is unlikely to be of benefit.

13 DESCRIPTION

Tamsulosin hydrochloride is an antagonist of alpha1a adrenoceptors in the prostate.

Tamsulosin hydrochloride is a white, crystalline powder that melts with decomposition at approximately 230°C. It is sparingly soluble in water and methanol, slightly soluble in glacial acetic acid and ethanol, and practically insoluble in ether.
The empirical formula of tamsulosin hydrochloride is C_{20}H_{37}N_{10}O_{8}·HCl. The molecular weight of tamsulosin hydrochloride is 444.98. Its structural formula is:

Each FLOMAX capsule for oral administration contains tamsulosin hydrochloride, USP 0.4 mg, and the following inactive ingredients: microcrystalline cellulose; methacrylic acid copolymer dispersion; titanium dioxide; calcium stearate; talc; gelatin; iron oxide; FD&C blue No. 2; titanium dioxide; propylene glycol; and shellac.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The effects of food on the pharmacokinetics of tamsulosin hydrochloride are consistent with the results presented in Table 2.

12.2 Pharmacodynamics

The pharmacokinetics of tamsulosin hydrochloride have been evaluated in adult healthy volunteers and patients with BPH after single and/or multiple administration with doses ranging from 0.1 mg to 1 mg.

Absorption

Absorption of tamsulosin hydrochloride from FLOMAX capsules 0.4 mg is essentially complete (>90%) following oral administration under fasting conditions. Tamsulosin hydrochloride exhibits linear kinetics following single and multiple dosing, with achievement of steady-state concentrations by the fifth day of once-a-day dosing.

Effect of Food

The time to maximum concentration (T_max) is reached by 4 to 5 hours under fasting conditions and by 6 to 7 hours when FLOMAX capsules are administered with food. Taking FLOMAX capsules under fasted conditions results in a 30% increase in bioavailability (AUC) and 40% to 70% increase in peak concentrations (C_max) compared to fed conditions (Figure 1).

Figure 1: Mean Plasma Tamsulosin Hydrochloride Concentrations Following Single-Dose Administration of FLOMAX Capsules 0.4 mg Under Fasted and Fed Conditions (n=8)

The effects of food on the pharmacokinetics of tamsulosin hydrochloride are consistent regardless of whether a FLOMAX capsule is taken with a light breakfast or a high-fat breakfast (Table 2).

Table 2: Mean (± S.D.) Pharmacokinetic Parameters Following FLOMAX Capsules 0.4 mg Once Daily or 0.8 mg Once Daily with a Light Breakfast, High-Fat Breakfast or Fasted (continued)

<table>
<thead>
<tr>
<th>Pharmacokinetic Parameter</th>
<th>0.4 mg OD to healthy volunteers; n=23 (age range 18–32 years)</th>
<th>0.8 mg OD to healthy volunteers; n=22 (age range 55–75 years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Light Breakfast</td>
<td>Fasted</td>
</tr>
<tr>
<td>C_max (ng/mL)</td>
<td>10.1 ± 4.8</td>
<td>18.1 ± 17.1</td>
</tr>
<tr>
<td>T_max (hours)</td>
<td>6.0</td>
<td>4.0</td>
</tr>
<tr>
<td>τ (hours)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>AUC (ng·h/mL)</td>
<td>151 ± 81.5</td>
<td>199 ± 94.1</td>
</tr>
</tbody>
</table>

The results of two-way in vitro studies indicate that the binding of tamsulosin hydrochloride to human plasma proteins is not affected by amitriptyline, diclofenac, glyburide, simvastatin plus simvastatin-hydroxy acid metabolite, warfarin, diazepam, propranolol, trichlormethiazide, or chloromadinone. Likewise, tamsulosin hydrochloride had no effect on the extent of binding of these drugs.

Distribution

The mean steady-state apparent volume of distribution of tamsulosin hydrochloride after intravenous administration to 10 healthy male adults was 16 L, which is suggestive of distribution into extracellular fluids in the body.

Tamsulosin hydrochloride is extensively bound to human plasma proteins (94% to 99%), primarily alpha, acid glycoprotein (AAG), with linear binding over a wide concentration range (20 to 600 ng/mL). The results of tamsulosin hydrochloride to human plasma proteins is not affected by amitriptyline, diclofenac, glyburide, simvastatin plus simvastatin-hydroxy acid metabolite, warfarin, diazepam, propranolol, trichlormethiazide, or chloromadinone. Likewise, tamsulosin hydrochloride had no effect on the extent of binding of these drugs.

Metabolism

There is no enantiomeric bioconversion from tamsulosin hydrochloride [R(-) isomer] to the S(+) isomer in humans. Tamsulosin hydrochloride is extensively metabolized by cytochrome P450 enzymes in the liver and less than 10% of the dose is excreted in urine unchanged. However, the pharmacokinetics of the metabolites of tamsulosin hydrochloride in humans has not been established. Tamsulosin is extensively metabolized, mainly by CYP3A4 and CYP2D6 as well as via some minor participation of other CYP isoenzymes. Inhibition of hepatic drug-metabolizing enzymes may lead to increased exposure to tamsulosin [see Warnings and Precautions (5.2) and Drug Interactions (7.1)]. The metabolites of tamsulosin hydrochloride undergo extensive conjugation to glucuronide or sulfate prior to renal excretion.

Excretion

On administration of the radiolabeled dose of tamsulosin hydrochloride to 4 healthy volunteers, 97% of the administered radioactivity was recovered, with urine (76%) representing the primary route of excretion compared to feces (21%) over 168 hours. Following intravenous or oral administration of an immediate-release formulation, the elimination half-life of tamsulosin hydrochloride in plasma ranged from 5 to 7 hours. Because of absorption rate-controlled pharmacokinetics with FLOMAX capsules, the apparent half-life of tamsulosin hydrochloride is approximately 9 to 13 hours in healthy volunteers and 14 to 15 hours in the target population.

Tamsulosin hydrochloride undergoes restrictive clearance in humans, with a relatively low systemic clearance (2.88 L/h).

Specific Populations

Pediatric use

FLOMAX capsules are not indicated for use in pediatric populations [see Use in Specific Populations (8.4)] at the currently recommended dosage for BPH. The safety and effectiveness of tamsulosin hydrochloride have not been established in children less than 12 years of age.

Geriatric (age) use

Cross-study comparison of FLOMAX capsules overall exposure (AUC) and half-life indicates that the pharmacokinetic disposition of tamsulosin hydrochloride may be slightly prolonged in geriatric males compared to young, healthy male volunteers. Intracranial pressure is independent of tamsulosin hydrochloride binding to AAG, but diminishes with age, resulting in a 40% overall higher exposure (AUC) in subjects of age 55 to 75 years compared to subjects of age 20 to 32 years [see Use in Specific Populations (8.5)].

Renal impairment

The pharmacokinetics of tamsulosin hydrochloride have been compared in 6 subjects with mild-moderate (30% to 50% CrCl, <70 mL/min/1.73 m²) or moderate-severe (10% to 30% CrCl, <30 mL/min/1.73 m²) renal impairment and 6 normal subjects (CrCl >90 mL/min/1.73 m²). While a change in the overall plasma concentration of tamsulosin hydrochloride was observed as the result of altered binding to AAG, the unbound (active) concentration of tamsulosin hydrochloride, as well as renal clearance, remained constant. Therefore, patients with renal impairment do not require an adjustment in FLOMAX capsules dosing. However, patients with end-stage renal disease (CrCl <10 mL/min/1.73 m²) have not been studied [see Use in Specific Populations (8.6)].
Hepatic impairment

The pharmacokinetics of tamsulosin hydrochloride have been compared in 8 subjects with moderate hepatic impairment (Child-Pugh’s classification: Grades A and B) and 8 normal subjects. While a change in the overall plasma concentration of tamsulosin hydrochloride was observed as the result of altered binding to AAG, the unbound (active) concentration of tamsulosin hydrochloride does not change significantly, with only a modest (32%) change in Cmax and AUC of tamsulosin by a factor of 1.3 and 1.6, respectively [see Warnings and Precautions (5.2) and Drug Interactions (7.1)]. A similar increase in exposure is expected in CYP2D6 poor metabolizers (PM) as compared to extensive metabolizers (EM). A fraction of the population (about 7% of Caucasians and 2% of African Americans) can be CYP2D6 PMs. Since CYP2D6 PMs cannot be readily identified and the potential for significant increase in tamsulosin exposure exists when FLOMAX 0.4 mg is coadministered with strong CYP3A4 inhibitors in CYP2D6 PMs. FLOMAX capsules 0.4 mg should not be used in combination with strong inhibitors of CYP3A4 (e.g., ketoconazole) [see Warnings and Precautions (5.2) and Drug Interactions (7.1)].

The effects of coadministration of a moderate CYP2D6 inhibitor (e.g., terbinafine) on the pharmacokinetics of FLOMAX have not been evaluated [see Warnings and Precautions (5.2) and Drug Interactions (7.1)].

The effects of paroxetine (a strong inhibitor of CYP2D6) at 20 mg once daily for 7 days on the pharmacokinetics of a single FLOMAX capsule 0.4 mg dose was investigated in 10 healthy volunteers (age range 21 to 38 years). Treatment with paroxetine resulted in an increase in the Cmax and AUC of tamsulosin by a factor of 2.2 and 4.6 respectively [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)].

Drug Interactions

Cytochrome P450 inhibition

Strong and moderate inhibitors of CYP3A4 or CYP2D6

The effects of ketoconazole (a strong inhibitor of CYP3A4) at 400 mg once daily for 5 days on the pharmacokinetics of a single FLOMAX capsule 0.4 mg dose was investigated in 24 healthy volunteers (age range 23 to 47 years). Concomitant treatment with ketoconazole resulted in an increase in the Cmax and AUC of tamsulosin by a factor of 2.2 and 2.8, respectively [see Warnings and Precautions (5.2) and Clinical Pharmacology (12.3)].

The effects of concomitant administration of a moderate CYP3A4 inhibitor (e.g., erythromycin) on the pharmacokinetics of FLOMAX have not been evaluated [see Warnings and Precautions (5.2) and Drug Interactions (7.1)].

The effects of paroxetine (a strong inhibitor of CYP2D6) at 20 mg once daily for 7 days on the pharmacokinetics of a single FLOMAX capsule 0.4 mg dose was investigated in 24 healthy volunteers (age range 23 to 47 years). Concomitant treatment with paroxetine resulted in an increase in the Cmax and AUC of tamsulosin by a factor of 1.3 and 1.6, respectively [see Warnings and Precautions (5.2) and Drug Interactions (7.1)]. A similar increase in exposure is expected in CYP2D6 poor metabolizers (PM) as compared to extensive metabolizers (EM). A fraction of the population (about 7% of Caucasians and 2% of African Americans) can be CYP2D6 PMs. Since CYP2D6 PMs cannot be readily identified and the potential for significant increase in tamsulosin exposure exists when FLOMAX 0.4 mg is coadministered with strong CYP3A4 inhibitors in CYP2D6 PMs. FLOMAX capsules 0.4 mg should not be used in combination with strong inhibitors of CYP3A4 (e.g., ketoconazole) [see Warnings and Precautions (5.2) and Drug Interactions (7.1)].

Cimetidine

The effects of cimetidine at 800 mg four times daily for 13 days on the pharmacokinetics of FLOMAX have not been evaluated [see Warnings and Precautions (5.2) and Drug Interactions (7.1)].

The effects of coadministration of both a CYP3A4 and a CYP2D6 inhibitor with FLOMAX capsules have not been evaluated. However, there is a potential for significant increases in tamsulosin exposure when FLOMAX 0.4 mg is coadministered with a combination of both CYP3A4 and CYP2D6 inhibitors [see Warnings and Precautions (5.2) and Drug Interactions (7.1)].

Other alpha adrenergic blocking agents

The pharmacokinetic and pharmacodynamic interactions between FLOMAX capsules and other alpha adrenergic blocking agents have not been determined; however, interactions between FLOMAX capsules and other alpha adrenergic blocking agents may be expected [see Warnings and Precautions (5.2) and Drug Interactions (7.2)].

PDE5 inhibitors

Caution is advised when alpha adrenergic blocking agents, including FLOMAX, are coadministered with PDE5 inhibitors. Alpha-adrenergic blockers and PDE5 inhibitors are both vasoconstrictors that can lower blood pressure. Concomitant use of these two drug classes can potentially cause symptomatic hypotension [see Warnings and Precautions (5.2) and Drug Interactions (7.3)].

Warfarin

A definitive drug-drug interaction study between tamsulosin hydrochloride and warfarin was not conducted. Results from limited in vitro and in vivo studies are inconclusive. Therefore, caution should be exercised with concomitant administration of warfarin and FLOMAX capsules [see Warnings and Precautions (5.2) and Drug Interactions (7.4)].

Nifedipine, atenolol, enalapril

In three studies in hypertensive subjects (age range 47 to 79 years) whose blood pressure was maintained in clinical trials, with the atenolol, enalapril, or nifedipine alone, the Cmax and AUC of FLOMAX capsules 0.4 mg for 7 days followed by FLOMAX capsules 0.8 mg for another 7 days (n=8 per study) resulted in no clinically significant effects on blood pressure and pulse rate compared to placebo (n=4 per study). Therefore, dosage adjustments are not necessary when FLOMAX capsules are administered concomitantly with nifedipine, atenolol, or enalapril [see Drug Interactions (7.5)].

Doxazosin and theophylline

In two studies in healthy volunteers (n=10 per study; age range 19 to 39 years) receiving FLOMAX capsules 0.4 mg/day for 2 days, followed by FLOMAX capsules 0.8 mg/day for 5 to 8 days, single intravenous dosages of doxazosin 0.5 mg or theophylline 5 mg/kg resulted in no change in the pharmacokinetics of doxazosin or theophylline. Therefore, dosage adjustments are not necessary when a FLOMAX capsule is administered concomitantly with doxazosin or theophylline [see Drug Interactions (7.6)].

Furosemide

The pharmacokinetic and pharmacodynamic interaction between FLOMAX capsules 0.8 mg once daily and furosemide 80 mg intravenously (single dose) was evaluated in 10 healthy volunteers (age range 21 to 40 years). FLOMAX capsules had no effect on the pharmacodynamics (excretion of electrolytes) of furosemide. While furosemide produced an 11% to 12% reduction in tamsulosin hydrochloride Cmax and AUC, these changes were not significant and do not require adjustment of the FLOMAX capsules dosage [see Drug Interactions (7.7)].

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Rats administered doses up to 43 mg/kg/day in males and 52 mg/kg/day in females had no increases in tumor incidence, with the exception of a modest increase in the frequency of mammary gland fibroadenomas in female rats receiving doses ≥5.4 mg/kg (P<0.0015). The highest doses of tamsulosin hydrochloride evaluated in the rat carcinogenicity study produced systemic exposures (AUC) in rats 3 times the exposures in men receiving the maximum therapeutic dose of 0.8 mg/day.

Mice were administered doses up to 127 mg/kg/day in males and 158 mg/kg/day in females. There were no significant tumor findings in male mice. Female mice treated for 2 years with the two highest doses of 45 and 156 mg/kg/day had statistically significant increases in the incidence of mammary gland fibroadenomas (P<0.0001) and adenocarcinomas (P<0.0075). The highest dose levels of tamsulosin hydrochloride evaluated in the mice carcinogenicity study produced systemic exposures (AUC) in mice 8 times the exposures in men receiving the maximum therapeutic dose of 0.8 mg/day.

The increased incidences of mammary gland neoplasms in female rats and mice were considered secondary to tamsulosin hydrochloride-induced hyperprolactinemia. It is not known if FLOMAX capsules elevate prolactin in humans. The relevance of human risk of the findings of prolactin-mediated endocrine tumors in rodents is not known.

Tamsulosin hydrochloride produced no evidence of mutagenic potential in vitro in the Ames reverse mutation test, mouse lymphoma thymidine kinase assay, unscheduled DNA repair synthesis assay, and chromosomal aberration assays in Chinese hamster ovary cells or human lymphocytes. There were no mutagenic effects in the in vivo sister chromatid exchange (SCE) and mouse micronucleus assays.

Studies in rats revealed significantly reduced fertility in males dosed with single or multiple daily doses of 300 mg/kg/day of tamsulosin hydrochloride (AUC exposure in rats at about 50 times the human exposure with the maximum therapeutic dose). The mechanism of decreased fertility in male rats is considered to be an effect of the compound on the vaginal mucosa with possible effects on the vaginal plug formation process. Female fertility was also decreased in rats coadministered with PDE5 inhibitors. Alpha-adrenergic blockers and PDE5 inhibitors are known to be potent smooth muscle relaxants, which evaluated irritative (frequency, urgency, and nocturia), and obstructive (hesitancy, incomplete emptying, intermittency, and weak stream) symptoms, where a decrease in score is consistent with improvement in symptoms; and 2) peak urine flow rate, where an increase in peak urine flow rate value over baseline is consistent with decreased urinary obstruction.

Mean changes from baseline to Week 13 in total AUA Symptom Score were significantly greater for groups treated with FLOMAX capsules 0.4 mg and 0.8 mg once daily compared to placebo in both U.S. studies (Table 3, Figures 2A and 2B). The changes from baseline to Week 13 in peak urine flow rate were also significantly greater for the FLOMAX capsules 0.4 mg and 0.8 mg once daily groups compared to placebo in Study 1, and for the FLOMAX capsules 0.8 mg once-daily group in Study 2 (Table 3, Figures 3A and 3B). Overall there were no significant differences in improvement observed in total AUA Symptom Scores or peak urine flow rates between the 0.4 mg and the 0.8 mg dose groups with the exception that the 0.8 mg dose in Study 1 had a significantly greater improvement in total AUA Symptom Score compared to the 0.4 mg dose.
Table 3: Mean (±S.D.) Changes from Baseline to Week 13 in Total AUA Symptom Score and Peak Urine Flow Rate (mL/sec)

<table>
<thead>
<tr>
<th></th>
<th>Total AUA Symptom Score</th>
<th>Peak Urine Flow Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean Baseline Value</td>
<td>Mean Change</td>
</tr>
<tr>
<td>Study 1†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FLOMAX capsules 0.8 mg once daily</td>
<td>19.9 ± 4.9 n=247</td>
<td>-9.6‡ ± 6.7 n=237</td>
</tr>
<tr>
<td>FLOMAX capsules 0.4 mg once daily</td>
<td>19.8 ± 5.0 n=254</td>
<td>-8.3‡ ± 6.5 n=246</td>
</tr>
<tr>
<td>Placebo</td>
<td>19.6 ± 4.9 n=254</td>
<td>-5.5 ± 6.6 n=246</td>
</tr>
</tbody>
</table>

Study 2§

|                       |                         |                      |                     |                      |
| FLOMAX capsules 0.8 mg once daily | 18.2 ± 5.6 n=244       | -5.8‡ ± 6.4 n=238    | 9.96 ± 3.16 n=244   | 1.79‡ ± 3.36 n=237   |
| FLOMAX capsules 0.4 mg once daily | 17.9 ± 5.8 n=248       | -5.1‡ ± 6.4 n=244    | 9.94 ± 3.14 n=246   | 1.52 ± 3.64 n=244    |
| Placebo               | 19.2 ± 6.0 n=239        | -3.6 ± 5.7 n=235     | 9.95 ± 3.12 n=239   | 0.93 ± 3.28 n=235    |

Week 13: For patients not completing the 13-week study, the last observation was carried forward.

*Total AUA Symptom Scores ranged from 0 to 35.
†Peak urine flow rate measured 4 to 8 hours post dose at Week 13.
‡Statistically significant difference from placebo (p-value ≤0.050; Bonferroni-Holm multiple test procedure).
§Peak urine flow rate measured 24 to 27 hours post dose at Week 13.

Mean total AUA Symptom Scores for both FLOMAX capsules 0.4 mg and 0.8 mg once-daily groups showed a rapid decrease starting at 1 week after dosing and remained decreased through 13 weeks in both studies (Figures 2A and 2B).

In Study 1, 400 patients (53% of the originally randomized group) elected to continue in their originally assigned treatment groups in a double-blind, placebo-controlled, 40-week extension trial (138 patients on 0.4 mg, 135 patients on 0.8 mg, and 127 patients on placebo). Three hundred twenty-three patients (43% of the originally randomized group) completed one year. Of these, 81% (97 patients) on 0.4 mg, 74% (75 patients) on 0.8 mg, and 56% (57 patients) on placebo had a response ≥25% above baseline in total AUA Symptom Score at one year.

Figure 2A: Mean Change from Baseline in Total AUA Symptom Score (0–35) Study 1

* indicates significant difference from placebo (p-value ≤0.050).
B = Baseline determined approximately one week prior to the initial dose of double-blind medication at Week 0.
Subsequent values are observed cases.
LOCF = Last observation carried forward for patients not completing the 13-week study.
Note: Patients in the 0.8 mg treatment group received 0.4 mg for the first week.

Figure 2B: Mean Change from Baseline in Total AUA Symptom Score (0–35) Study 2

* indicates significant difference from placebo (p-value ≤0.050).
B = Baseline determined approximately one week prior to the initial dose of double-blind medication at Week 0.
Subsequent values are observed cases.
LOCF = Last observation carried forward for patients not completing the 13-week study.
Note: Patients in the 0.8 mg treatment group received 0.4 mg for the first week.
Note: Total AUA Symptom Scores range from 0 to 35.

Figure 3A: Mean Increase in Peak Urine Flow Rate (mL/Sec) Study 1

* indicates significant difference from placebo (p-value ≤0.050).
B = Baseline determined approximately one week prior to the initial dose of double-blind medication at Week 0.
Subsequent values are observed cases.
LOCF = Last observation carried forward for patients not completing the 13-week study.
Note: Patients in the 0.8 mg treatment group received 0.4 mg for the first week.

Figure 3B: Mean Increase in Peak Urine Flow Rate (mL/Sec) Study 2

* indicates significant difference from placebo (p-value ≤0.050).
B = Baseline determined approximately one week prior to the initial dose of double-blind medication at Week 0.
Subsequent values are observed cases.
LOCF = Last observation carried forward for patients not completing the 13-week study.
Note: Patients in the 0.8 mg treatment groups received 0.4 mg for the first week.

16 HOW SUPPLIED/STORAGE AND HANDLING
FLOMAX capsules 0.4 mg are supplied in high density polyethylene bottles containing 100 hard gelatin capsules with olive green opaque cap and orange opaque body. The capsules are imprinted on one side with Flomax 0.4 mg and on the other side with BI 58. FLOMAX capsules 0.4 mg, 100 capsules (NDC 0024-5837-01)
Store at 25°C (77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].
Keep FLOMAX capsules and all medicines out of reach of children.

17 PATIENT COUNSELING INFORMATION
Advise the patient to read the FDA-approved patient labeling (Patient Information).
• Hypotension
Advise the patient about the possible occurrence of symptoms related to postural hypotension, such as dizziness, when taking FLOMAX capsules, and they should be...
cautioned about driving, operating machinery, or performing hazardous tasks [see Warnings and Precautions (5.1)].

• Drug Interactions
Advise the patient that FLOMAX should not be used in combination with strong inhibitors of CYP3A4 [see Warnings and Precautions (5.2) and Drug Interactions (7.1)].

• Priapism
Advise the patient about the possibility of priapism as a result of treatment with FLOMAX capsules and other similar medications. Patients should be informed that this reaction is extremely rare, but if not brought to immediate medical attention, can lead to permanent erectile dysfunction (impotence) [see Warnings and Precautions (5.3)].

• Screening for Prostate Cancer
Prostate cancer and BPH frequently coexist; therefore, screen patients for the presence of prostate cancer prior to treatment with FLOMAX capsules and at regular intervals afterwards [see Warnings and Precautions (5.4)].

• Intraoperative Floppy Iris Syndrome
Advise the patient when considering cataract or glaucoma surgery to tell their ophthalmologist that they have taken FLOMAX capsules [see Warnings and Precautions (5.5)].

• Administration
Advise the patient that FLOMAX capsules should not be crushed, chewed or opened [see Dosage and Administration (2)].

FDA-approved Patient Labeling
Patient labeling is provided as a tear-off leaflet at the end of this prescribing information.

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PATIENT INFORMATION
Flomax® (Flo-max)
(tamsulosin hydrochloride, USP)
Capsules, 0.4 mg
Read the Patient Information that comes with FLOMAX capsules before you start taking it and each time you refill your prescription. The information may have changed. This leaflet does not take the place of discussions with your doctor about your medical condition or your treatment.

What is FLOMAX?
FLOMAX is a prescription alpha-blocker medicine used to treat the signs and symptoms of benign prostatic hyperplasia (BPH), a condition your doctor may refer to as an enlarged prostate.

• FLOMAX is not for women.
• FLOMAX is not for children.

Who should not take FLOMAX?
Do not take FLOMAX capsules if you are allergic to any of its ingredients. See the end of this leaflet for a complete list of ingredients in FLOMAX capsules.

What should I tell my doctor before using FLOMAX?
Before taking FLOMAX capsules, tell your doctor about all your medical conditions, including:
• any kidney or liver problems.
• any history of low blood pressure.
• any allergies to sulfa or any other medicines.
• if you are planning to have cataract or glaucoma surgery.

Tell your doctor about all the medicines you take, including:
• any prescription medicines, including blood pressure medicines.
• any non-prescription medicines, including vitamins and herbal supplements.

Some of your other medicines may affect the way FLOMAX capsules work. Especially tell your doctor if you take a medicine for high blood pressure. You should not take FLOMAX if you are already taking certain blood pressure medicines.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take FLOMAX?
• Take FLOMAX exactly as prescribed by your doctor.
• Do not crush, chew, or open FLOMAX capsules.
• Take FLOMAX one time each day, about 30 minutes after the same meal each day. For example, you may take FLOMAX 30 minutes after dinner each day.

• If you miss a dose of FLOMAX, take it as soon as you remember. If you miss your dose for the whole day, continue with your next dose on your regular schedule. Do not take two doses at the same time.
• If you stop or forget to take FLOMAX for several days, talk with your doctor before starting again.
• If you take more FLOMAX capsules than prescribed, call your doctor right away.

What are the possible side effects of FLOMAX capsules?
Possible side effects of FLOMAX may include:
• Decreased blood pressure when changing positions. FLOMAX capsules may cause a sudden drop in blood pressure upon standing, especially after the first dose or when changing doses.
  Symptoms may include:
  • fainting
  • dizziness
  • lightheadedness
  Change positions slowly from lying down to sitting up or from a sitting to a standing position until you learn how you react to FLOMAX capsules. If you begin to feel dizzy, sit or lie down until you feel better. If the symptoms are severe or do not improve, call your doctor.
• Allergic reactions. Make your doctor aware of any allergic reactions you may experience while taking FLOMAX.
  Allergic reactions may include:
  • rash
  • itching
  • hives
  Rare and more serious allergic reactions may also occur. Get medical help right away if you have any of the following reactions:
  • swelling of face, tongue, or throat
  • difficulty breathing
  • blistering of the skin
  • A painful erection that will not go away. FLOMAX capsules can cause a painful erection (priapism), which cannot be relieved by having sex. If this happens, get medical help right away. If priapism is not treated, you may not be able to get an erection in the future.
  • Eye problems during cataract or glaucoma surgery. During cataract or glaucoma surgery, a condition called intraoperative floppy iris syndrome (IFIS) can happen if you take or have taken FLOMAX capsules. If you need to have cataract or glaucoma surgery, be sure to tell your surgeon if you take or have taken FLOMAX capsules.

Common side effects of FLOMAX capsules may include:
• runny nose
• dizziness
• decreased semen
These are not all the possible side effects with FLOMAX capsules. Tell your doctor if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088, or by visiting www.fda.gov/medwatch.

What should I avoid while taking FLOMAX capsules?
Avoid driving, operating machinery, or other dangerous activities, until you know how FLOMAX affects you. FLOMAX capsules may cause a sudden drop in blood pressure upon standing, especially after the first dose or when changing doses. See “What are the possible side effects of FLOMAX capsules?”

How do I store FLOMAX capsules?
Store FLOMAX capsules at Room Temperature 68°F to 77°F (20°C to 25°C). Short-term exposure to higher or lower temperatures (from 59°F [15°C] to 86°F [30°C]) is acceptable. Ask your doctor or pharmacist if you have any questions about storing your capsules.

Keep FLOMAX capsules and all medicines out of the reach of children.

General information
This medicine was prescribed for you by your doctor for your condition. Do not use it for another condition. Do not give FLOMAX to other people, even if they have the same symptoms that you have. It may harm them.
While taking FLOMAX, you must have regular checkups. Follow your doctor’s advice about when to have these checkups.

BPH can occur with other more serious conditions, including prostate cancer. Therefore, ask your doctor about screening for prostate cancer prior to treatment with FLOMAX capsules and at regular intervals afterwards.

This patient information leaflet summarizes the most important information about FLOMAX. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about FLOMAX that is written for health professionals. For current prescribing information, access www.4flomax.com or call sanofi-aventis U.S. LLC at 1-800-633-1610.

What are the ingredients in FLOMAX capsules?
- Active Ingredient: tamsulosin hydrochloride, USP
- Inactive Ingredients: microcrystalline cellulose; methacrylic acid copolymer dispersion; triacetin; calcium stearate; talc; gelatin; iron oxide; FD&C blue No. 2; titanium dioxide; propylene glycol; and shellac.

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This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: January 2019

TAM-FPLR-SL-JAN19 Rx Only