The efficacy of doxazosin mesylate was evaluated extensively in over 900 patients with BPH in double-blind, placebo-controlled studies. Doxazosin mesylate results in a reduction in systemic vascular resistance. In patients with hypertension, the 4 mg tablet contains FD&C yellow #6 Aluminum Lake; the 8 mg tablet contains FD&C yellow #6 Aluminum Lake. The results from three placebo-controlled studies (N=609) showed significant efficacy with 4 mg and 8 mg doxazosin mesylate.

Uroflowmetric evaluations were performed at times of peak (2-6 hours post-dose) and/or trough (24 hours post-dose). The maximum flow rate was seen with doxazosin mesylate in Studies 1 and 2, compared to 0.1-0.7 mL/sec with placebo.

**Change in Maximum Flow Rate (mL/sec) in 24-Hour Uroflowmetry Studies**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Patients (N=85)</th>
<th>Placebo (N=183)</th>
<th>4 mg Doxazosin Mesylate</th>
<th>8 mg Doxazosin Mesylate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Placebo</td>
<td>4 mg Doxazosin</td>
<td>8 mg Doxazosin Mesylate</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mesylate 4 mg</td>
<td>Mesylate 8 mg</td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>47</td>
<td>38</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td>Change</td>
<td>14.9</td>
<td>-4.7</td>
<td>9.8</td>
<td>+2.3</td>
</tr>
<tr>
<td>Least squares mean</td>
<td>0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>10.3</td>
<td>11.3</td>
<td>7.2</td>
<td>7.8</td>
</tr>
<tr>
<td>Change from Baseline</td>
<td>14.9</td>
<td>-4.7</td>
<td>9.8</td>
<td>+2.3</td>
</tr>
</tbody>
</table>

**Changes from Baseline to 24-Hour Uroflowmetry Studies**

Changes from baseline to 24-hour uroflowmetry studies in different treatment groups show significant improvements with doxazosin mesylate compared to placebo.

**Pharmacokinetics**

Doxazosin mesylate is absorbed rapidly after oral administration. Bioavailability is approximately 65%, reflecting first pass metabolism of doxazosin by the liver. The effect of food on the pharmacokinetics of doxazosin mesylate in young (<65 years) and elderly (≥65 years) patients was evaluated.

**Warnings**

- **Orthostatic Hypotension:** Doxazosin mesylate should be used with caution in patients with conditions that may be associated with cardiovascular instability. Orthostatic symptoms, especially at the initiation of therapy, and urged to avoid driving or hazardous tasks for 24 hours after the last dose.
- **Contraindications:** Doxazosin mesylate is contraindicated in patients with severe cardiovascular disease.
- **Precautions:** Patients should be advised about the seriousness of the condition (see PRECAUTIONS). Use of doxazosin mesylate with cimetidine (see PRECAUTIONS, Drug Interactions) must be avoided.

**Adverse Effects**

Doxazosin mesylate has been associated with a variety of adverse effects, including headache, dizziness, lightheadedness, or palpitations. If these effects are bothersome, they should be reported to the physician, so that dose adjustments can be made.

**Indications**

- **Benign Prostatic Hyperplasia (BPH):** Doxazosin mesylate is used to treat both benign prostatic hyperplasia (BPH) and high blood pressure (hypertension).

**Drug Interactions**

- **Cimetidine:** Avoid concomitant use of doxazosin mesylate with cimetidine.
- **Warfarin:** Doxazosin mesylate does not affect the plasma concentration of prostate specific antigen (PSA).

**Usage**

- **Pediatric Use:** Doxazosin mesylate has not been studied in children under the age of 18 years.
- **Geriatric Use:** Doxazosin mesylate is not recommended for patients over the age of 80 years.

**How to Take Doxazosin Mesylate and What You Should Know While Taking Doxazosin Mesylate for BPH**

- **Before starting treatment:** Consult your doctor about any concerns you may have about taking doxazosin mesylate. Your doctor may recommend checking your blood pressure before starting your treatment.

**Summary**

Doxazosin mesylate is an effective treatment for both benign prostatic hyperplasia (BPH) and high blood pressure (hypertension). It is important to consult with your healthcare provider about the potential benefits and risks of this medication.
Doxazosin Mesylate Can Cause a Sudden Drop in Blood Pressure After the VERY FIRST DOSE. You may feel dizzy, faint or “light-headed,” especially after you stand up from a lying or sitting position. This is more likely to occur if you take the first few doses or if you increase your dose, but can occur at any time while you are taking the drug. If you take the first few doses, you should sit or lie down slowly after standing to avoid the potential for too sudden a drop in blood pressure and being dizzy or faint. After the first few doses of doxazosin mesylate you can be dizzy or faint while standing up from a lying or sitting position. Doxazosin mesylate has been known to cause fainting in patients who get up quickly from a lying or sitting position. Your blood pressure should be checked when you start taking Doxazosin mesylate even if you do not have high blood pressure (hypertension). Your doctor will discuss with you the details of how your blood pressure is measured.

Blood Pressure Measurement: Whatever equipment is used, it is usual for your blood pressure to be measured in the following way: measure your blood pressure after lying quietly on your back for five minutes. Then, after standing for two minutes measure your blood pressure again. Your doctor will discuss with you what other times during the day your blood pressure will be measured. Note that readings at high intensity exercise can, over a period of time, lower your average blood pressure.

You can take Doxazosin mesylate either in the morning or at bedtime and it will be equally effective. If you take Doxazosin mesylate at bedtime but need to get up from bed to go to the bathroom, get up slowly and cautiously until you are sure the medication affects you. It is important to get up slowly from a chair or bed at any time until you know how you react to Doxazosin mesylate. You should not follow your usual bedtime routine until you know that you can tolerate the medication. If you begin to feel dizzy, sit or lie down to help your body to relax.

• You will start with a 1 mg dose of Doxazosin mesylate once daily. Then the once daily dose will be increased as your body gets used to the effects of the medication. After one week, your doctor may increase your dose gradually and again be cautious about possible adverse effects. Do not discontinue Doxazosin mesylate before you have consulted your doctor. It was prescribed only for you.

• Other side effects you could have while taking Doxazosin mesylate, in addition to lowering of the blood pressure, include dizziness, palpitations, fatigue, nasal stuffiness. Most side effects are mild. However, you should consult your doctor if the side effects do not disappear with your usual bedtime routine.

• WARNING: Extremely rarely, Doxazosin mesylate and similar medications have caused partial or total occlusion of the heart and other blood vessels in sexual intercourse or masturbation. This condition is serious and it is estimated that it can be followed by death. Call your doctor or go to an emergency room as soon as possible.

• Tell your surgeon if you take or have taken Doxazosin mesylate or you may have a prolonged abnormal erection, call your doctor or go to an emergency room as soon as possible.

• Increases in dose beyond 4 mg increase lowering effects and symptomatic hypotension; therefore, PDE-5 inhibitor therapy should be initiated at the lowest dose possible.

Experience with doxazosin mesylate overdosage is limited. Two adolescents who each intentionally ingested 40 mg of doxazosin mesylate were studied. Both adolescents developed hypotension. One adolescent developed liver dysfunction and required hospitalization. The safety and effectiveness of doxazosin mesylate as an antihypertensive agent have not been established.

Nursing Mothers: Doxazosin mesylate has been administered to approximately 4000 hypertensive patients, of whom 1679 were included in placebo-controlled studies. In placebo-controlled studies, adverse effects occurred in 49% of these patients, and was similar to that in the placebo-controlled studies. Follow your doctor’s instructions about breastfeeding.

ADVERSE REACTIONS

The most common side effects seen in clinical trials were:

• Postural Hypertension 0.3% 0%

• Flatulence 1% 1%

• Nausea 3% 4%

• Dizziness † 15.6% * 9.0%

• Thirst 1% 0%

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