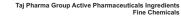
Read the Medication Guide provided by your pharmacist before you start using duloxetine and each time you get a refill. If you have any questions, consult your doctor or pharmacist. Take this medication by mouth with or without food, usually 1 or 2 times a day or as directed by your doctor. Swallow the capsule whole. Do not crush or chew the capsule or mix the contents with food or liquid. Dosage is based on your medical condition and response to treatment.





Active Pharmaceuticals Ingredients Manufacturers

## Taj Pharmaceuticals Ltd. **Doxazosin Mesylate** CAS No.: 74191-85-8

Doxazosin Mesylatea quinazoline compoundis an alpha blocker used to treat high blood pressure and benign prostatic hyperplasia.

#### Systematic (IUPAC) name

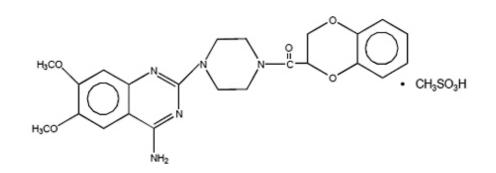
2-{4-[(2,3-dihydro-1,4-benzodioxin-2-yl)carbonyl]piperazin-1-yl}-6,7-dimethoxyquinazolin-4-amine

#### Identifiers

CAS number 74191-85-8 ATC code C02CA04 PubChem 3157 DrugBank APRD00474

#### **Chemical data**

Formula C23H25N5O5 Mol. mass 451.475 g/mol Pharmacokinetic data **Bioavailability 65%** Protein binding 98% Metabolism Hepatic Half life 22 hours



#### DOSAGE

This medication can be taken with or without food.

Doxazosin mesylate should be taken exactly as prescribed, even if your symptoms have disappeared. Try not to miss any doses. If Doxazosin mesylate is not taken regularly, your condition may worsen.

If you have benign prostatic hyperplasia, you should see improvement in a week. Blood pressure will fall in 2 to 6 hours.

If you miss a dose Take it as soon as you remember. If it is almost time for your next dose, skip the one you missed and go back to your regular schedule. Never take 2 doses at the same time.

Take this medication exactly as prescribed. Try to take it at the same time each day. Take the first dose at bedtime to minimize the chances of getting dizzy or fainting. It is important to continue taking this medication even if you feel well. Most people with high blood pressure do not feel sick. Do not stop taking this medication without consulting your doctor. Some conditions may become worse when the drug is abruptly stopped. Your dose may need to be gradually decreased.

#### SIDE EFFECTS

Dizziness, drowsiness, lightheadedness, headache, constipation, loss of appetite, dry mouth, tiredness, stuffy nose, blurred vision, dry eyes or trouble sleeping may occur the first several days as your body adjusts to the medication. If any of these effects continue or become bothersome, inform your doctor. Notify your doctor if you experience: chest pain, depression, swelling of hands or feet, sexual problems. Tell your doctor immediately if any of these highly unlikely but very serious side effects occur: persistent sore throat, fever, easy bleeding or bruising, nausea, stomach pain, yellowing eyes or skin, dark urine.



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### Taj Pharmaceuticals Ltd. Doxazosin Mesylate

#### CAS No 74191-85-8

Males - though it is unlikely to occur, if you get a painful, prolonged erection, stop using this drug and seek immediate medical attention. In the unlikely event you have a serious allergic reaction to this drug, seek immediate medical attention. Symptoms of a serious allergic reaction include: rash, itching, swelling, severe dizziness, trouble breathing.

Common reactions include dizziness, fatigue, headache, shortness of breath, diarrhea, abdominal pain, edema (fluid accumulation) and low blood pressure. Doxazosin causes significant reduction in blood pressure after administration of the first dose (first dose effect). This reduction in blood pressure may be associated with dizziness and fainting, especially when rising from a sitting position. To avoid this, patients should rise slowly from a sitting position, start treatment with the 1 mg dose, and then doses should be adjusted upwards slowly. Priapism (painful, prolonged penile erection) and a reduction in white blood cells have been associated with doxazosin.

#### USES

Doxazosin is used alone or in combination with other drugs to treat hypertension (high blood pressure). It works by relaxing blood vessels so blood can flow more easily. Lowering high blood pressure helps prevent strokes, heart attacks, and kidney problems.

This medication is also used in men to treat the symptoms of a prostate gland condition called BPH (benign prostatic hyperplasia, also known as enlarged prostate). It does not shrink the prostate, but it works by relaxing the muscles in the bladder neck and prostate. Relaxing these muscles leads to relief of symptoms of BPH such as the feeling of needing to urinate frequently or urgently, weak stream, difficulty in beginning the flow of urine, and the need to urinate during the middle of the night.

Doxazosin belongs to a class of medications called alpha blockers.

#### HOW TO USE

Take this medication by mouth with or without food, usually once daily or as directed by your doctor. To avoid injury related to dizziness or fainting, take your first dose of doxazosin at bedtime. Your dose may be gradually increased. Take your first new dose at bedtime when your dose is increased unless directed otherwise by your doctor.

Dosage is based on your medical condition and response to therapy.

Use this medication regularly to get the most benefit from it. To help you remember, take it at the same time each day. It is important to continue taking this medication even if you feel well. Most people with high blood pressure do not feel sick.

Do not stop taking this medication without consulting your doctor. Some conditions may become worse when the drug is abruptly stopped. Your dose may need to be gradually decreased.

#### PRECAUTIONS

Before taking doxazosin, tell your doctor or pharmacist if you are allergic to it; or to other alpha blockers such as prazosin and terazosin; or if you have any other allergies.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: prostate cancer, heart disease (e.g., congestive heart failure, angina, heart attack in last 6 months), liver disease, kidney disease.

\To minimize dizziness and lightheadedness, get up slowly when rising from a sitting or lying position, especially when you first start taking this drug or whenever your doctor changes your dose. Also, when you first start taking this drug, avoid situations where you may be injured if you faint. Taj Group of Companies INDIA



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# Taj Pharmaceuticals Ltd.Doxazosin Mesylate<br/>CAS No. : 74191-85-8Image: Case of the state of the state

This drug may make you dizzy or drowsy. Use caution while driving, using machinery, or doing any activity that requires alertness. Limit alcoholic beverages.

Before having surgery (including cataract eye surgery), tell your doctor or dentist that you are taking this medication.

The elderly may be at greater risk for dizziness and low blood pressure while using this drug.

#### **MISSED DOSE**

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up. Check with your doctor if you miss 2 or more doses.

#### STORAGE

Store at room temperature below 86 degrees F (30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets.

#### **DRUG DESCRIPTION**

Doxazosin Mesylateis a quinazoline compound that is a selective inhibitor of the alpha1 subtype of alpha-adrenergic receptors. The chemical name of doxazosin mesylate is 1-(4-amino-6,7-dimethoxy-2-quinazolinyl)-4-(1,4-benzodioxan-2-ylcarbonyl) piperazine methanesulfonate. The empirical formula for doxazosin mesylate is C23H25N5O5 • CH4O3S and the molecular weight is 547.6.

Doxazosin mesylate is freely soluble in dimethylsulfoxide, soluble in dimethylformamide, slightly soluble in methanol, ethanol, and water (0.8% at 25°C), and very slightly soluble in acetone and methylene chloride. Doxazosin mesylate is available as colored tablets for oral use and contains 1 mg (white), 2 mg (yellow), 4 mg (orange) and 8 mg (green) of doxazosin as the free base.

The inactive ingredients for all tablets are: microcrystalline cellulose, lactose, sodium starch glycolate, magnesium stearate and sodium lauryl sulfate. The 2 mg tablet contains D & C yellow 10 and FD & C yellow 6; the 4 mg tablet contains FD & C blue 10 and D & C yellow 10.

Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export \*\*\* subjected to your country government laws /control substance ACT.

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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at: http://www.tajapi.com or by contacting the sponsor, Taj Pharmaceuticals Limited., at: 91 022 30601000. This leaflet was prepared by Taj Pharmaceuticals Limited, Mumbai (India). MPSTJ278 Last revised: 29 August 2009



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