PATIENT INFORMATION

Doxazosin Tablets (dox az' oh sin mes' i late)

Dispense with Patient Information available at www1.apotex.com/products/us

What are doxazosin tablets?

Doxazosin tablets are a prescription medicine that contains doxazosin mesylate and is called an "alpha-blocker". Doxazosin tablets are used to treat:

- the symptoms of benign prostatic hyperplasia (BPH)
- high blood pressure (hypertension)

It is not known if doxazosin tablets are safe and effective in children.

Who should not take doxazosin tablets?

Do not take doxazosin tablets if you:

• are allergic to doxazosin, other quinazolines, or any of the ingredients in doxazosin tablets. See the end of this Patient Information leaflet for a complete list of ingredients in doxazosin tablets.

What should I tell my healthcare provider before taking doxazosin tablets? Before taking doxazosin tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have had low blood pressure, especially after taking other medicine. Signs of low blood pressure include fainting, dizziness, and lightheadedness.
- have any planned eye surgery
- have prostate cancer or a history of prostate cancer. Your healthcare provider may have you checked for prostate cancer before you start taking and while you take doxazosin tablets.
- have liver problems
- are pregnant or plan to become pregnant. It is not known if doxazosin tablets will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if doxazosin passes into your breastmilk. Talk to your healthcare provider about the best way to feed your baby if you take doxazosin tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Doxazosin tablets may affect the way other medicines work, and other medicines may affect the way doxazosin tablets work causing side effects. **Especially tell your healthcare provider if you take:**

• other medicine for high blood pressure medicine to treat erectile dysfunction (ED) called a phosphodiesterase type 5 (PDE-5) inhibitor. The use of doxazosin tablets with PDE-5 inhibitors can lead to a drop in blood pressure or to fainting.

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

How should I take doxazosin tablets?

- Take doxazosin tablets exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much doxazosin tablets to take and when to take it.
- Your healthcare provider may need to change your dose of doxazosin tablets until it is the right dose for you.

What should I avoid while taking doxazosin tablets?

Do not drive or perform any hazardous task until at least 24 hours after you have taken doxazosin tablets if you are taking:

- your first dose of doxazosin tablets
- Doxazosin tablets for the first time after your healthcare provider has increased your dose of doxazosin tablets
- Doxazosin tablets for the first time after any breaks (interruptions) in your treatment with doxazosin tablets

What are the possible side effects of doxazosin tablets?

Doxazosin tablets may cause serious side effects, including:

- A sudden drop in blood pressure, especially when you first start treatment or when there is an increase in your dose of doxazosin tablets, is common but can also be serious. This may cause you to faint, or to feel dizzy or lightheaded. Your risk of having this problem may be increased if you take doxazosin tablets with certain other medicines that lower blood pressure including PDE-5 inhibitors. Your healthcare provider may monitor your blood pressure while you take doxazosin tablets. See "What should I avoid while taking doxazosin tablets?"
- Eye problems during cataract surgery. A condition called Intraoperative Floppy Iris Syndrome (IFIS) can happen during cataract surgery if you take or have taken alpha-blockers such as doxazosin tablets. If you need to have cataract surgery, be sure to tell your healthcare provider if you take or have taken doxazosin tablets.
- A painful erection that will not go away. Doxazosin tablets 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.

The most common side effects of doxazosin tablets are:

 weakness or lack of energy (asthenia) dizziness

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of doxazosin tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of doxazosin tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use doxazosin tablets for a condition for which it was not prescribed. Do not give doxazosin tablets to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about doxazosin tablets. For more information, ask your healthcare provider. You can ask your healthcare provider or pharmacist for information that is written for healthcare professionals.

What are the ingredients in doxazosin tablets?

Active ingredient: doxazosin mesylate

Inactive ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

APOTEX INC.
DOXAZOSIN TABLETS, USP
1 mg, 2 mg, 4 mg and 8 mg

Manufactured by Manufactured for

Apotex Inc. Apotex Corp.
Toronto, Ontario Weston, Florida

Canada M9L 1T9 33326

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