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Dispense with Patient Information available at:
<https://www.sunpharma.com/usa/products>

PATIENT INFORMATION

Alfuzosin Hydrochloride Extended-Release Tablets, USP (al-FUE-zoe-sin HYE-droe-KLOR-ide)

Read the Patient Information that comes with alfuzosin hydrochloride extended-release tablets before you start using it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your condition or your treatment. You and your doctor should talk about all your medicines, including alfuzosin hydrochloride extended-release tablets, now and at your regular checkups.

What is the most important information I should know about alfuzosin hydrochloride extended-release tablets?

Alfuzosin hydrochloride extended-release tablets can cause serious side effects, including a sudden drop in blood pressure, especially when you start treatment. This may cause you to faint, or to feel dizzy or lightheaded.

- Your risk of having this problem may be increased if you take alfuzosin hydrochloride extended-release tablets with certain other medicine that lowers blood pressure:
 - medicines for high blood pressure
 - a nitrate medicine for angina

Ask your doctor if you are not sure if you are taking one of these medicines.

- **Do not drive, operate machinery, or do any dangerous activities until you know how alfuzosin hydrochloride extended-release tablets affect you.** This is especially important if you already have a problem with low blood pressure or take medicines to treat high blood pressure.
- If you begin to feel dizzy or lightheaded, lie down with your legs and feet up. If your symptoms do not improve call your doctor.

See the section “What are the possible side effects of alfuzosin hydrochloride extended-release tablets?” for more information about side effects.

What is alfuzosin hydrochloride extended-release tablet?

Alfuzosin hydrochloride extended-release tablet is a prescription medicine that is called an “alpha-blocker”. Alfuzosin hydrochloride extended-release tablet is used in adult men to treat the symptoms

of benign prostatic hyperplasia (BPH). Alfuzosin hydrochloride extended-release tablets may help to relax the muscles in the prostate and the bladder which may lessen the symptoms of BPH and improve urine flow.

Before prescribing alfuzosin hydrochloride extended-release tablets, your doctor may examine your prostate gland and do a blood test called a prostate specific antigen (PSA) test to check for prostate cancer. Prostate cancer and BPH can cause the same symptoms. Prostate cancer needs a different treatment.

Alfuzosin hydrochloride extended-release tablets are not for use in women or children.

Some medicines called “alpha-blockers” are used to treat high blood pressure. Alfuzosin hydrochloride extended-release tablets are not for the treatment of high blood pressure.

Who should not take alfuzosin hydrochloride extended-release tablets?

Do not take alfuzosin hydrochloride extended-release tablets if you:

- have certain liver problems
- take antifungal medicines like ketoconazole (Nizoral*) or itraconazole (Sporanox*)
- take anti-HIV medicines like ritonavir (Norvir*, Kaletra*)
- are allergic to alfuzosin hydrochloride or any of the ingredients in alfuzosin hydrochloride extended-release tablets. See the end of this leaflet for a complete list of ingredients in alfuzosin hydrochloride extended-release tablets.

Before taking alfuzosin hydrochloride extended-release tablets, tell your doctor if you:

- have liver problems
- have kidney problems
- have had low blood pressure, especially after taking another medicine. Signs of low blood pressure are fainting, dizziness, and lightheadedness.
- have a heart problem called angina
- or any family members have a rare heart condition known as congenital prolongation of the QT interval.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Some of your other medicines may affect the way alfuzosin hydrochloride extended-release tablets works and cause serious side effects. See “What is the most important information I should know about alfuzosin hydrochloride extended-release tablets?”

Especially tell your doctor if you take:

- another alpha blocker medicine
- a medicine to treat high blood pressure
- a medicine to treat angina

- a medicine to treat erectile dysfunction (ED)
- the antifungal medicines like ketoconazole (Nizoral*) or itraconazole (Sporanox*)
- the anti-HIV medicine like , ritonavir (Norvir*, Kaletra*)

Ask your doctor or pharmacist if you are not sure if your medicine is one of those listed above.

What you need to know while taking alfuzosin hydrochloride extended-release tablets?

- If you have an eye surgery for cataract (clouding of the eye) planned, tell your ophthalmologist that you are using alfuzosin hydrochloride extended-release tablets or have previously been treated with an alpha-blocker.

How do I take alfuzosin hydrochloride extended-release tablets?

- Alfuzosin hydrochloride extended-release tablets come in child-resistant package.
- Take alfuzosin hydrochloride extended-release tablet exactly as your doctor prescribes it.
- Take alfuzosin hydrochloride extended-release tablet after the same meal each day. Do not take it on an empty stomach.
- Swallow the alfuzosin hydrochloride extended-release tablet whole. Do not crush, split, or chew alfuzosin hydrochloride extended-release tablets.
- If you take too many alfuzosin hydrochloride extended-release tablets call your local poison control center or emergency room right away.

What are the possible side effects of alfuzosin hydrochloride extended-release tablets?

Alfuzosin hydrochloride extended-release tablets can cause serious side effects, including:

- **See “What is the most important information I should know about alfuzosin hydrochloride extended-release tablets?”**
- **A painful erection that will not go away.** Alfuzosin hydrochloride extended-release 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 with alfuzosin hydrochloride extended-release tablets are:

- dizziness
- headache
- tiredness

Call your doctor if you get any side effect that bothers you.

These are not all the side effects of alfuzosin hydrochloride extended-release tablets. For more information ask your doctor or pharmacist.

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

How do I store alfuzosin hydrochloride extended-release tablets?

- Store alfuzosin hydrochloride extended-release tablets at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F).
- Protect from light and moisture.

Keep alfuzosin hydrochloride extended-release tablets and all medicines out of the reach of children.

General information about alfuzosin hydrochloride extended-release tablets:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use alfuzosin hydrochloride extended-release tablets for a condition for which it was not prescribed. Do not give alfuzosin hydrochloride extended-release tablets to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about alfuzosin hydrochloride extended-release tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about alfuzosin hydrochloride extended-release tablets that is written for health professionals.

You may also call 1-800-818-4555

What are the ingredients of alfuzosin hydrochloride extended-release tablets?

Active Ingredient: alfuzosin hydrochloride, USP

Inactive Ingredients: pregelatinized maize starch, hypromellose, hydroxypropyl cellulose, basic butylated methacrylate copolymer, colloidal silicon dioxide, magnesium stearate, and talc.

* All trademark names are the property of their respective owners.

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