

PATIENT INFORMATION

Alfuzosin hydrochloride extended-release tablets, USP

Read the Patient Information that comes with alfuzosin hydrochloride 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, now and at your regular checkups.

What is the most important information I should know about alfuzosin hydrochloride?

Alfuzosin hydrochloride 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 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 affects 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?” for more information about side effects.

What is alfuzosin hydrochloride?

Alfuzosin hydrochloride is a prescription medicine that is called an “alpha-blocker”. Alfuzosin hydrochloride is used in adult men to treat the symptoms of benign prostatic hyperplasia (BPH). Alfuzosin hydrochloride 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, 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 is not for use in women or children.

Some medicines called “alpha-blockers” are used to treat high blood pressure.

Alfuzosin hydrochloride is not for the treatment of high blood pressure.

Who should not take alfuzosin hydrochloride?

Do not take alfuzosin hydrochloride 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. See the end of this leaflet for a complete list of ingredients in alfuzosin hydrochloride.

Before taking alfuzosin hydrochloride, 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 works and cause serious side effects.

See “What is the most important information I should know about alfuzosin hydrochloride?”

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 tablets

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

How do I take alfuzosin hydrochloride tablets?

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

What are the possible side effects of alfuzosin hydrochloride?

Alfuzosin hydrochloride can cause serious side effects, including:

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

- Store alfuzosin hydrochloride tablets at 20° to 25°C (68° to 77°F) [see USP].
- Protect from light and moisture.

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

General information about alfuzosin hydrochloride:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use alfuzosin hydrochloride for a condition for which it was not prescribed. Do not give alfuzosin hydrochloride 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. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about alfuzosin hydrochloride that is written for health professionals.

You may also visit our website at www.exelanpharma.com or call 1-855-295-7455.

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

Active Ingredient: alfuzosin hydrochloride, USP

Inactive Ingredients: microcrystalline cellulose (NF), guar gum (NF), hydroxypropyl methyl cellulose (USP), colloidal silicon dioxide (NF) and magnesium stearate (NF).

Rx Only

Manufactured for:
Exelan Pharmaceuticals, Inc.
Lawrenceville, GA 30046

Manufactured by:
InvaGen Pharmaceuticals, Inc.
Hauppauge, NY 11788

Rev: 08/14