

Package leaflet: Information for the user

Alfuzosin Orion 2.5 mg film-coated tablets

alfuzosin hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Alfuzosin Orion is and what it is used for
2. What you need to know before you take Alfuzosin Orion
3. How to take Alfuzosin Orion
4. Possible side effects
5. How to store Alfuzosin Orion
6. Contents of the pack and other information

1. What Alfuzosin Orion is and what it is used for

Alfuzosin Orion belongs to a group of medicines called alpha-1-blockers. Alfuzosin Orion is used to treat moderate to severe symptoms of Benign Prostatic Hyperplasia. This is a condition where the prostate gland enlarges (hyperplasia), but the growth in itself is not cancerous (it is benign). It is more common in older men.

The prostate gland is situated under the bladder surrounding the urethra (the tube that takes your urine to the outside of the body). With age, the prostate gland may grow and press on the urethra making it smaller. This may cause problems with urination such as frequent urination and difficulty in passing urine.

Alfuzosin works by relaxing the prostate gland muscle. This reduces the narrowing of the urethra and so makes it easier to pass urine.

2. What you need to know before you take Alfuzosin Orion

Do not take Alfuzosin Orion

- if you are allergic to alfuzosin or any of the other ingredients of this medicine (listed in section 6). Symptoms of an allergic reaction include: rash, swelling of your lips, throat, or tongue, difficulty in swallowing or breathing.
- if you have, or have had in the past, low blood pressure when standing up from a sitting or lying position (the medical term for this is orthostatic hypotension). It can make you feel dizzy, light-headed or faint when you stand or sit up quickly.
- if you have severe liver problems
- if you are already taking another alpha-1-blocker (such as terazosin, doxazosin). See section below on “Other medicines and Alfuzosin Orion”. If in doubt please ask your pharmacist or doctor.
- if you are taking ritonavir alone or in combination with ombitasvir/paritaprevir, lopinavir, nirmatrelvir. See section “Other medicines and Alfuzosin Orion” below.

Warnings and precautions

Talk to your doctor or pharmacist before taking your medicine if:

- you have a heart disease
- you have chest pain (angina)
- you are known to have an abnormality of electrocardiogram (ECG), called “QT prolongation”.
- you have had a stroke or short-lasting symptoms similar to stroke, there is a risk of decreased blood flow to parts of the brain.

Some patients, particularly those who are also taking medicine for high blood pressure or medicines for chest pain (angina pectoris) may get dizziness, weakness or sweating within a few hours of taking a dose. If this happens, you should lie down until the symptoms have completely disappeared. Let your doctor know as he may decide to adjust your dose.

In case of an erection (often painful), unrelated to sexual activity, that persists longer than 4 hours you should contact a doctor or go to a hospital immediately because you may need treatment. See the section below “possible side effects”.

Other medicines and Alfuzosin Orion

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is because Alfuzosin Orion can affect the way some other medicines work. Some medicines can also have an effect on the way that Alfuzosin Orion works.

Do not take Alfuzosin Orion if you are taking:

- other alpha-blockers such as doxazosin, indoramin, prazosin, terazosin, tamsulosin or phenoxybenzamine.
- ritonavir whether taken alone or in combination with lopinavir (commonly used for treatment of HIV) or ritonavir in combination with ombitasvir/paritaprevir (commonly used for treatment of Chronic Hepatitis C infection) or ritonavir in combination with nirmatrelvir (commonly used for treatment of mild to moderate COVID-19).

Talk to your doctor or pharmacist before taking your medicine if:

- in the past, you have had a large fall in blood pressure while taking an alpha-blocker (this could include previous use of alfuzosin). See paragraph immediately above for examples of other alpha-blockers.
- you are taking a medicine for high blood pressure, as you may get dizzy, weak or start sweating within a few hours of taking this medicine. If this happens, lie down until the symptoms have completely gone. Tell your doctor as the dose of your medicine may be changed.
- you are taking medicines for chest pain (angina)
- you are taking medicines for fungal infections (such as, itraconazole)
- you are taking medicines for bacterial infections (such as clarithromycin, telithromycin)
- you are taking medicines for treatment of depression (such as nefazodone)
- you are taking ketoconazole tablets (used to treat Cushing’s syndrome - when the body produces an excess of cortisol).

Operations while taking Alfuzosin Orion

- if you are going to have an operation that needs a general anaesthetic, tell your doctor you are taking Alfuzosin Orion before the operation. This is because it can be dangerous as it can lower your blood pressure.
- if you are undergoing eye surgery because of cataract (cloudiness of the lens) please inform your eye specialist before the operation that you are using or have previously used Alfuzosin Orion. This is because Alfuzosin Orion may cause complications during the surgery which can be managed if your specialist is prepared in advance.

Driving and using machines

You may feel dizzy and weak while taking Alfuzosin Orion. If this happens do not drive or operate any tools or machines.

Alfuzosin Orion 2.5 mg film-coated tablet contains lactose

This medicine contains 58 mg lactose monohydrate per tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Other excipients

This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially 'sodium-free'.

3. How to take Alfuzosin Orion

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If you are starting the treatment, it is best if you take the first tablet before you go to bed.

Adults

The usual dose is one tablet three times daily. Your doctor may increase this to four times a day if needed.

Older patients (> 65 years) and patients taking other medicines for high blood pressure

The initial dose is one 2.5 mg tablet twice a day (morning and evening).

Patients with poor kidney function

The initial dose is one 2.5 mg tablet twice a day.

Patients with liver problems

The initial dose is one 2.5 mg tablet daily. Your doctor may increase this to one 2.5 mg tablet twice a day (in the morning and evening).

If you notice that Alfuzosin Orion has too strong or too weak an effect, consult your doctor or pharmacist.

Use in children

Alfuzosin Orion is not recommended for children (16 years or younger).

If you take more Alfuzosin Orion than you should

Contact your local hospital straight away. Tell the doctor how many tablets you have taken. Lie down as much as possible to help stop the side effects. Do not try to drive to the hospital yourself.

If you forget to take Alfuzosin Orion

Do not take a double dose to make up for a forgotten dose. Skip the missed dose and take the next tablet as directed.

If you stop taking Alfuzosin Orion

Keep taking your tablets, even if your symptoms improve. Only stop if your doctor tells you to. The symptoms are better controlled if you continue taking the same dose of this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. These side effects are most likely to happen at the start of treatment.

Stop taking Alfuzosin Orion and contact a doctor or go to a hospital immediately if you get any of the following serious side effects:

- **Chest pain (angina)** (*may affect up to 1 in 10 000 people*)

Normally, this only happens if you have had angina before. **If you get chest pain stop taking your tablets and contact a doctor or go to a hospital immediately.**

- **Severe allergic reactions** (*may affect up to 1 in 10 000 people*)

You could notice symptoms of angioedema, such as a red and lumpy skin rash, swelling (on the eyelids, face, lips, mouth and tongue), difficulty breathing or swallowing. These are symptoms of an allergic reaction. **If this happens, stop taking your tablets and contact a doctor or go to a hospital immediately.**

- **Persistent erection (priapism)**

Priapism is an abnormal, often painful, persistent erection of the penis unrelated to sexual activity. **If you would get an erection such as the one described here that would persist longer than 4 hours, contact a doctor or go to a hospital immediately because you may need treatment.** This condition can lead to permanent impotence if not properly treated.

Other side effects include:

Common (*may affect up to 1 in 10 people*)

- feeling dizzy
- headache
- general feeling of being unwell
- feeling dizzy or lightheaded when you stand or sit up quickly
- feeling sick (nausea)
- dry mouth
- diarrhoea
- stomach pain
- weakness or tiredness.

Uncommon (*may affect up to 1 in 100 people*)

- drowsiness
- visual disturbances (changes in your vision or sight)
- fast heart beat (tachycardia), palpitations (pounding in the chest and irregular heart beat)
- fainting
- lack of control over passing urine
- runny nose, itching, sneezing, and stuffy nose
- uncomfortable feeling in the stomach and indigestion (dyspepsia)
- being sick (vomiting)
- rash and itching
- hot flushes
- water retention (may cause swollen arms or legs)
- chest pain.

Additional side effects

Not Known (frequency cannot be estimated from the available data):

- irregular and fast heart beat
- decrease blood flow to parts of the brain in patients known to have vascular disturbances in the brain
- decrease in white blood cells. Signs may include more frequent infections, sore throat or mouth ulcers.
- low numbers of blood platelets. Signs may include bleeding from your gums and nose, bruising, prolonged bleeding from cuts, rash (pinpoint red spots called petechia).
- abnormal liver function (liver problem). Signs may include yellowing of your skin or the whites of your eyes.
- if you are undergoing eye surgery because of cataract (cloudiness of the lens) and are using or have previously used Alfuzosin Orion, the pupil may dilate poorly and the iris (the coloured circular part of the eye) may become floppy during the procedure. This only occurs during the operation and it is important for the eye specialist to be aware of this possibility as the operation may need to be performed differently (see section “Operations while taking Alfuzosin Orion”).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Alfuzosin Orion

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister, bottle or carton. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Alfuzosin Orion contains

- The active substance is alfuzosin hydrochloride. Each film-coated tablet contains 2.5 mg alfuzosin hydrochloride.
- The other ingredients are in tablet core: sodium starch glycolate (Type A), microcrystalline cellulose, lactose monohydrate, povidone, magnesium stearate and in film-coating: hypromellose, macrogols and titanium dioxide (E171).

What Alfuzosin Orion looks like and contents of the pack

Film-coated tablet.

White to off-white round, biconvex, film-coated tablets debossed with ‘X’ on one side and ‘31’ on other side. Diameter of the tablet is 6.1 mm.

Pack-sizes:

Blister pack: 30 and 90 tablets

Bottle pack: 100 tablets.

Not all pack sizes may be marketed.

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This leaflet was last revised on 2025-11-14