

**prolonged-release tablets****Alfuzosin hydrochloride****Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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**1. WHAT ALFUZOSINA PH&T IS AND WHAT IT IS USED FOR**

ALFUZOSINA PH&T contains the active ingredient alfuzosin which belongs to a group of medicines called alpha-adrenoreceptor antagonists or "alpha-blockers". Alfuzosin is used to treat the symptoms of a condition called Benign Prostatic Hyperplasia (BPH). BPH means that the prostate gland enlargens (hypertrophy) but the growth is not cancerous (it is benign). The symptoms include frequent trips to the toilet to pass water (especially at night), difficulty in passing water and a feeling of not completely emptying your bladder.

Alfuzosin works by relaxing the muscles in the prostate gland and bladder, making it easier to pass water.

**2. BEFORE YOU TAKE ALFUZOSINA PH&T****Do not take ALFUZOSINA PH&T**

- if you are allergic (hypersensitive) to alfuzosin or other "alpha-blockers" (e.g. terazosin, doxazosin)
- if you are allergic to any of the other ingredients of ALFUZOSINA PH&T (these are listed in section 6 Further Information)
- if you have ever fainted or felt dizzy when sitting up or standing up suddenly
- if you have liver problems
- if you are taking any other medicines called "alpha blockers" (e.g. terazosin, doxazosin)

**Take special care with ALFUZOSINA PH&T**

Talk to your doctor if any of the following applies to you:

- if you have severe kidney problems
- if you are taking medicines to treat high blood pressure. Your doctor will check your blood pressure regularly, especially at the start of treatment
- if you experience a sudden drop in blood pressure when you stand up. This can result in dizziness, weakness or sweating within a few hours of taking ALFUZOSINA PH&T. In such cases, you should lie down until the symptoms have totally disappeared. These effects are usually temporary and occur at the start of treatment
- if you have previously been treated with an alpha-blocker and it caused a significant drop in your blood pressure. Your doctor will start treatment with alfuzosin at a low dose and will gradually increase the dose depending on how you get on
- if you suffer from acute heart failure
- if you suffer from congenital QTc prolongation, or you have a known history of acquired QTc prolongation or you are taking drugs known to increase the QTc interval. Your doctor should evaluate before and during the administration of alfuzosin.

- If you suffer from coronary disease, the specific treatment for coronary insufficiency should be continued. If angina pectoris reappears or worsens, alfuzosin should be discontinued

- if you suffer from chest pain (angina) and you are being treated with a "nitrate". Taking alfuzosin may increase the risk of your blood pressure dropping

- 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 used ALFUZOSINA PH&T. This is because ALFUZOSINA PH&T may cause complications during the surgery which can be managed if your specialist is prepared in advance.

The tablet should be swallowed whole. You should not crunch, crush, chew, grind or pound to powder. This may lead to inappropriate release and absorption of the drug and therefore possible early side effects.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is especially important to tell your doctor if you are taking any of the following as they may interact with your medicine:

- ketoconazole and itraconazole (medicines used to treat fungal infections)
- ritonavir (medicine used to treat HIV)
- medicines to lower blood pressure
- medicines (nitrates) used to treat the symptoms of chest pain (angina).

The concomitant use of ALFUZOSINA PH&T with medicines to treat high blood pressure or chest pain may lead to low blood pressure.

ALFUZOSINA PH&T must not be taken with other "alpha1-blockers" such as terazosin or doxazosin.

If you are going to have an operation requiring the administration of anaesthetics, please tell your doctor that you are taking ALFUZOSINA PH&T.

**Taking ALFUZOSINA PH&T with food and drink**

ALFUZOSINA PH&T should be taken after a meal.

**Driving and using machines**

At the start of treatment with ALFUZOSINA PH&T, you may feel light headed, dizzy or faint. If you are affected in this way, you should not drive or use machinery or perform any hazardous tasks until the symptoms have passed.

**Important information about some of the ingredients of ALFUZOSINA PH&T**

This medicine contains a small amount of lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**3. HOW TO TAKE ALFUZOSINA PH&T**

Always take ALFUZOSINA PH&T exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**How many tablets should you take?**

The usual dose is one tablet daily taken after a meal.

On the first day, take the tablet at bedtime. Then take the tablet at the same time each day, after a meal.

You should swallow the tablet whole with a glass of water.

Do not crush, chew or divide the tablets as too much of the active substance alfuzosin may reach your body too quickly. This may increase the risk of side effects.

Elderly patients (over 65 years) and patients with mild to moderate kidney problems:

Your doctor will start your treatment with a lower dose of alfuzosin. If it is well tolerated and you need a higher dose, the doctor will prescribe one ALFUZOSINA PH&T tablet daily.

**Use in children:**

Efficacy of alfuzosin has not been demonstrated in children aged 2 to 16 years. Therefore, alfuzosin is not indicated for use in paediatric population.

**FRONT**

**If you take more ALFUZOSINA PH&T than you should**

If you take large amounts of ALFUZOSINA PH&T your blood pressure may suddenly drop and you may feel dizzy or even faint. If you begin to feel dizzy, sit or lie down until you feel better. If the symptoms do not disappear, call your doctor as you may need to be treated in hospital.

**If you forget to take ALFUZOSINA PH&T**

Miss out that dose completely and take the next tablet at the usual time. Do not take a double dose to make up for a forgotten tablet as this may cause a sudden drop in your blood pressure, especially if you take blood pressure lowering medicines.

**If you stop taking ALFUZOSINA PH&T**

You should not stop taking the tablets without speaking to your doctor first. If you want to stop treatment or you have any further questions about your medicine, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, ALFUZOSINA PH&T can cause side effects, although not everybody gets them.

**All medicines can cause allergic reactions although serious allergic reactions are very rare. If you get a swollen face or throat after taking these tablets, tell your doctor immediately.**

**A common side effect when starting treatment is dizziness, especially when you are getting up from a chair or bed (postural hypotension). If you begin to feel light headed or dizzy, sit or lie down until you feel better.**

The following side effects have been reported. If any of these gets troublesome, talk to your doctor.

**Common side effects** (more than 1 in 100 and less than 1 in 10 patients):

- Tiredness
- Headache
- Dizziness
- Abdominal pain
- Indigestion
- Nausea (Feeling sick)
- Dry mouth
- Feeling of weakness
- Generally feeling unwell

**Uncommon side effects** (more than 1 in 1,000 and less than 1 in 100 patients)

- Feeling drowsy
- Eye problems
- Fast heartbeat
- Reddening of the face (flushing)
- Fainting (especially at beginning of the treatment)
- Runny nose
- Chest pain
- Diarrhoea
- Marked drop blood pressure (postural hypotension)
- Rash
- Itching
- Swelling of ankles and feet
- Incontinence
- Oedema
- Vertigo

**Very rare side effects** (more than 1 in 10,000 and less than 1 in 1,000 patients):

- Worsening or recurrence of chest pain (angina pectoris)
- Swelling of body in the whole (angioedema)
- Urticaria

**Frequency unknown** (cannot be estimated from the available data)

- Intraoperative floppy iris syndrome
- Change in the cardiac rhythm (atrial fibrillation)
- Vomiting
- Liver damage
- Decrease in white blood cells (neutropenia)
- Persistent and painful erection (priapism)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**5. HOW TO STORE ALFUZOSINA PH&T**

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use ALFUZOSINA PH&T after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. FURTHER INFORMATION****What ALFUZOSINA PH&T contains**

- The active substance is alfuzosin hydrochloride. Each prolonged-release tablet contains 10 mg of alfuzosin hydrochloride.
- The tablet core also contains lactose monohydrate, hypromellose, microcrystalline cellulose, povidone K25, colloidal anhydrous silica, magnesium stearate.
- The tablet coating contains poly(vinyl alcohol), titanium dioxide (E171), macrogol 4000, talc (E553b), ethylcellulose (20cP), medium-chain triglycerides, oleic acid.

**What ALFUZOSINA PH&T looks like and contents of the pack**

ALFUZOSINA PH&T, prolonged-release tablets are white, round, film-coated tablets.

They are available in PVC/PVDC-aluminium blister packs with 30 tablets.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorization Holder:  
PH&T S.p.A, Via Marostica, 1 – 20146 Milan (Italy)  
0039.02.438504.1  
0039.02.48195301  
[phtmilan@tin.it](mailto:phtmilan@tin.it)

**Manufacturers:**

- Kern Pharma, S.L., Venus 72, Polígono Ind. Colón II, 08228 Terrassa, Barcelona, Spain.
- MIPHARM S.p.A, via B. Quaranta, 12 – 20141 Milan, Italy

**This leaflet was last approved in**

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