

# ALFUTOR ER TABLETS

Alfuzosin Hydrochloride (10mg)

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## What Alfutor ER is used for

Treatment for symptoms of noncancerous enlarged prostate gland known as benign prostatic hypertrophy (BPH).

Adjuvant treatment to a catheter (thin tube that can be inserted in the body to treat diseases or perform a surgical procedure) in acute urinary retention related enlarged prostate gland.

## How Alfutor ER works

It belongs to a group of medicines called alpha-blockers. Alfuzosin Hydrochloride is used to treat moderate to severe symptoms of noncancerous enlarged prostate gland. This is a condition where the prostate gland enlarges (hyperplasia), but the growth in itself is not cancerous (benign). It occurs most often 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 the urethra making it smaller. This may cause problems with urination such as frequent urination and difficulty in passing urine. Alfuzosin Hydrochloride works by relaxing the prostate gland muscle. This reduces the narrowing of the urethra and so makes it easier to pass urine.

## Before you use Alfutor ER

### - When you must not use it

Do not take Alfutor ER:

- If you are allergic (hypersensitive) to Alfuzosin Hydrochloride or any of the other ingredients of Alfutor ER.
- Signs of an allergic reaction include: a rash, swallowing or

breathing problems, swelling of your lips, face, throat or tongue.

- If you are taking another alpha-blocker.
- If you have postural hypotension (occurs when a person's blood pressure falls when suddenly standing up from a lying or sitting position).
- If you have liver problems.
- If you have severe kidney failure (creatinine clearance <30 ml/min).
- In combination with ritonavir.
- In combination with telaprevir.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Alfutor ER.

### *Pregnancy and lactation*

Do not take Alfutor ER if you are pregnant or plan to become pregnant or think you might be pregnant.

Do not take Alfutor ER if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

### - Before you start use it

Seek advice from doctor or pharmacist before taking your medicine if:

- You have chest pain (angina).
- You have a condition where your kidneys are hardly working at all.
- You have heart problems, or if your heart suddenly stopped pumping efficiently (acute cardiac failure).
- You have hereditary problems with the way your heart beats (congenital QTc prolongation).
- You are over 65. This is due to the increased sensitivity to develop hypotension and related adverse reactions in elderly patients.
- You ever get painful erections of the penis, unrelated to sexual activity that will not go away, before or during treatment.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Alfutor ER.

### - Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

This includes medicines you buy without a prescription, including herbal medicines. This is because Alfutor ER can affect the way some other medicines work. Also some medicines can affect the way Alfutor ER works.

Do not take Alfutor ER if you are taking:

Other alpha-blockers such as:

- Doxazosin.
- Indoramin.
- Prazosin.
- Terazosin.
- Tamsulosin.
- Phenoxybenzamine.

Check with 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).
- Ritonavir (antiretroviral medication) used along with other medications to treat HIV/AIDS.
- 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 he or she may decide to change the dose of your medicine.
- Medicines for high blood pressure (hypertension).
- Medicines for chest pain (angina).
- Medicines for fungal infections (such as ketoconazole or itraconazole) and HIV (such as ritonavir).

## How to use Alfutor ER

### - How much to use

#### *Benign Prostatic Hyperplasia*

- The usual dose is one Alfutor ER tablet once a day.

#### *Acute Urinary Retention*

- Alfutor ER will be given to you by your doctor on the day you have the catheter inserted.
- You should continue taking Alfutor ER once a day.
- You should stop taking Alfutor ER the day after the catheter is removed (3-4 days in total).

# ALFUTOR ER TABLETS

Alfuzosin Hydrochloride (10mg)

## - When to use it

- Always take Alfutor ER exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- Swallow your tablets whole with plenty of water.
- Do not break, crush or chew your tablets. This can affect the release of your medicine into the body.
- Take this medicine immediately after the evening meal.

## - How long to use it

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 forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Do not take a double dose to make up for a forgotten tablet. Miss it out and go on as before.

## - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think that you may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. 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.

## While you are using it

### - Things you must do

- Take your medicine exactly as your doctor has told you.
- Swallow your tablets whole with plenty of water.
- Tell all the doctors, dentists and pharmacists that are treating you that you are taking Alfutor ER.
- Tell your doctor immediately if you become pregnant while taking this medication.

### *Operations and tests while taking Alfutor ER*

- If you are going to have an operation on the eye because of cataract (cloudiness of the eye'),

tell your eye specialist you are using or have used Alfutor ER in the past. This is because Alfutor ER may cause complications during your operation. This can be managed if your eye specialist knows before carrying out the operation.

- If you are being treated for high blood pressure, your doctor should measure your blood pressure regularly, especially at the start of treatment.
- If you are going to have an operation that needs a general anaesthetic, tell your doctor you are taking Alfutor ER before the operation. Your doctor may decide to stop you having Alfutor ER, 24 hours before the operation. This is because Alfutor ER can lower your blood pressure.

### - Things you must not do

- Do not break, crush or chew your tablets. This can affect the release of your medicine into the body.
- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Alfutor ER to anyone else, even if they have the same symptoms or condition as you.

### - Things to be careful of

#### *Driving and using machines*

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

## Side effects

Like all medicines, product name can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

These side effects are most likely to happen at the start of treatment.

- Chest pain (angina) 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.

- Allergic reactions. You could notice symptoms of angioedema, such as a red and lumpy skin rash, swelling (on the eyelids, face, lips, mouth and tongue), difficulty in 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.
- Painful erection of the penis (priapism): If you get painful erections of the penis, unrelated to sexual activity, that will not go away, stop taking your tablets and contact a doctor or go to a hospital immediately.

Other side effects include:

#### *Common*

- Feeling dizzy or faint.
- Headache.
- Feeling sick (nausea).
- Stomach pain.
- Weakness or tiredness.

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.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Consumers→Reporting→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

## Storage and Disposal of Alfutor ER

### - Storage

- Store below 30°C.
- Protect from moisture and light.

### - Disposal

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.

## Product Description

### - What it looks like

White to off white, round shape, flat face beveled edge tablets debossed with

# ALFUTOR ER TABLETS

Consumer Medication Information leaflet (RiMUP)

Alfuzosin Hydrochloride (10mg)

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'1021' on one side and '10' on other side.

## Ingredients

Active ingredient

- Alfuzosin Hydrochloride.

Inactive ingredients

- Anhydrous Lactose (Pharmatose DCL-21).
- Colloidal Silicone Dioxide.
- Hypromellose K100M CR.
- Isopropyl Alcohol.
- Magnesium Stearate.
- Povidone (K30).
- Povidone K90D (40 mesh).
- Talc.

- MAL number:

MAL17107014AZ

## **Manufacturer**

TORRENT PHARMACEUTICALS LTD.

Indrad 382 721, District: Mehsana INDIA.

## **Product Registration Holder**

Laboratories Torrent (Malaysia) Sdn Bhd.

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Malaysia.

## **Date of revision**

26/02/2019

## **Serial Number**

NPRA(R2/1)190119/19