

# AFZOLINE XL 10mg Prolonged Release Tablet

Alfuzosin Hydrochloride 10mg

## What is in this leaflet

1. What AFZOLINE XL 10 mg Prolonged Release Tablet is used for
2. How AFZOLINE XL 10 mg Prolonged Release Tablet works
3. Before you use AFZOLINE XL 10 mg Prolonged Release Tablet
4. How to use AFZOLINE XL 10 mg Prolonged Release Tablet
5. While you are using AFZOLINE XL 10 mg Prolonged Release Tablet
6. Side effects
7. Storage and Disposal of AFZOLINE XL 10 mg Prolonged Release Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

## **What AFZOLINE XL 10 mg Prolonged Release Tablet is used**

-AFZOLINE XL 10 mg Prolonged Release Tablet can be used to treat the symptoms of **Benign Prostatic Hyperplasia**. This is when the prostate gland enlarges (hyperplasia) but the growth is not cancerous (it is benign). It can cause problems in passing water (urine).

-AFZOLINE XL 10 mg Prolonged Release Tablet can be used as adjuvant treatment to catheter in **Acute Urinary Retention** related to benign prostatic hypertrophy.

## **How AFZOLINE XL 10 mg Prolonged Release Tablet works**

- AFZOLINE XL 10 mg Prolonged Release Tablet belongs to a group of medicines called alpha-blockers.
- The prostate gland lies underneath the bladder. It surrounds the urethra. This is the tube that takes your water to the outside of the body.
- If the prostate gets bigger, it presses on the urethra making it narrower. This makes it difficult to pass water.
- Your tablets work by relaxing the prostate gland muscle. This allows the urethra to get wider and so makes it easier to pass water. In a few individual with benign prostatic hyperplasia, the prostate

gland gets so big that it stops the flow of urine completely.

This is called Acute Urinary Retention.

- This is very painful and you may need a short stay in hospital.
- A thin, flexible tube (catheter) is passed into the bladder. This drains the water and relieves the pain.
- During this time, AFZOLINE XL 10 mg Prolonged Release Tablet may be used to help the water to flow again.

## **Before you use AFZOLINE XL 10 mg Prolonged Release Tablet**

### - When you must not use it

Do not take AFZOLINE XL 10 mg Prolonged Release Tablet if:

- You are allergic (hypersensitive) to Alfuzosin and/or any of the other ingredients of AFZOLINE XL 10 mg Prolonged Release Tablet (listed in section ingredients below)
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, throat, or tongue.
- You have something called postural hypotension. This is a drop in blood pressure which usually happens when you stand up. It can make you feel dizzy, light-headed or faint when you stand or sit up quickly.
- You have liver failure.
- You have severe kidney failure.
- You are taking Ritonavir-boosted protease inhibitor, Telaprevir. (see taking other medicines)

### - Before you start to use it

Take special care and check with your doctor before taking this medicine if:

- You have chest pain (angina).
- You are treated for your high blood pressure.
- You are pregnant or breastfeeding.
- You are having operation on your eyes.
- You have heart problems.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking AFZOLINE XL 10 mg Prolonged Release Tablet.

### - Taking other medicines

Do not take this medicine and tell your doctor if you are taking:

- Ritonavir-boosted protease inhibitor, Telaprevir.

Inadvisable combinations which you should tell your doctor if you are taking: Medicines used to treat high blood pressure (alpha-receptor blockers such as Tamsulosin).

- Medicines for fungal infections (such as Ketoconazole, Itraconazole)
- Medicines used to treat bacterial infections (such as Clarithromycin, Erythromycin)
- Medicines used to treat impotency, particularly in elderly (such as Vardenafil)

The following medicines need extra precautions for use in combination with AFZOLINE XL 10 mg Prolonged Release Tablet:

- Phosphodiesterase type 5 inhibitors used to treat impotence (such as Sildenafil and Tadalafil)

Your doctor might consider taking precaution with the following medicines in combination with AFZOLINE XL 10 mg Prolonged Release Tablet which may cause enhanced hypotension effect:

- Antihypertensives medicines except alpha-receptor blockers
- Nitrates, nitrites and related medicines used to prevent angina (chest pain) (such as Isosorbide dinitrate, Isosorbide, Linsidomine, Molsidomine, Nicorandil, and Nitroglycerin)

- 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 anesthetic, tell your doctor you are taking AFZOLINE XL 10 mg Prolonged Release Tablet before the operation.

Your doctor may decide to stop you having AFZOLINE XL 10 mg Prolonged Release Tablet before the operation. This is because it can be dangerous as it can contribute to blood pressure instability.

# AFZOLINE XL 10mg Prolonged Release Tablet

Alfuzosin Hydrochloride 10mg

## How to use AFZOLINE XL 10 mg Prolonged Release Tablet

Always take AFZOLINE XL 10 mg Prolonged Release Tablet exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Swallow your tablets orally in whole with a glass of water.
- Do not break, crush or chew your tablets. This can affect the release of your medicine into the body.

### - How much to use

#### Acute Urinary Retention

- AFZOLINE XL 10 mg Prolonged Release Tablet will be given to you by your doctor on the day you have the catheter inserted.
- The recommended dosage is one tablet per day.
- You should stop taking AFZOLINE XL 10 mg Prolonged Release Tablet one day after the catheter is removed (3-4 days in total).

#### Benign Prostatic Hyperplasia

- The usual dose is one AFZOLINE XL 10 mg Prolonged Release Tablet once a day.

### - When to use it

Take AFZOLINE XL 10 mg Prolonged Release Tablet at about the same time each day; immediate after your evening meal (after dinner) unless your doctor tells you otherwise.

### - How long to use it

Continue taking your medicine for as long as your doctor tells you.

### - If you forget to use it

- If you forget to take your tablet, leave 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.

### - If you use too much (overdose)

If you take too many tablets, contact your doctor or the nearest hospital emergency department immediately. Tell the doctor how many tablets you have taken. Lie down as much as possible to help stop the side effects (eg: low blood pressure). Do not try to drive to the hospital yourself.

## While you are using it

### - Things you must do

If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

### - Things you must not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking AFZOLINE XL 10 mg Prolonged Release Tablet, or change the dosage, without checking with your doctor.

### - Things to be careful of

#### Driving and using machines.

- You may feel dizzy, weak and vision disturbance. If you experience these side effects, do not drive or use any tools or machines, and tell your doctor straight away.

## Side effects

Like all medicines, AFZOLINE XL 10 mg Prolonged Release Tablet can cause side effects, although not everyone gets them.

### Do not be alarmed by this list of possible side effects.

You may not experience any of them.

### Tell your doctor immediately

**Common side effects** (affecting less than 1 in 10 people):

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

**Uncommon side effects** (affecting less than 1 in 100 people)

- Feeling dizzy or faint when you stand or sit up quickly (postural hypotension). If this occurs, you should remain lying down until the symptoms have completely subsided. These effects are usually transient, occur at the beginning of treatment and do not generally prevent continued treatment
- Fast heartbeat, pounding in the chest and uneven heartbeat.
- Chest pain.
- Drowsiness.
- Diarrhoea.

- Dry mouth.
- Rash and itching.
- Flushes.
- Water retention (may cause swollen arms or legs).

**Very rare side effects** (affects less than 1 in 10,000 people)

- Itchy, lumpy rash also called hives or nettle rash

**Other side effects** (frequency not known) which may occur are:

- A painful erection of the penis, unrelated to sexual activity that will not go away.
- Liver problems. Signs may include yellowing of your skin or the whites of your eyes.
- You may get more infections than usual. This could be caused by a decrease in the number of white blood cells.
- Vomiting

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 visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of AFZOLINE XL 10 mg Prolonged Release Tablet

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

### Storage

- Keep out of the reach and sight of children.
- Do not use AFZOLINE XL 10 mg Prolonged Release Tablet after the expiry date which is stated on the label or carton.
- Store in a cool place below 30°C. Protect from light.

### Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of

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medicines no longer required. These measures will help to protect the environment.

## Product Description

### - What it looks like?

Yellow, cylindrical-shaped tablet with engraved 10 on one side and plain on the other

### - Ingredients

#### - Active ingredient:

*Alfuzosin Hydrochloride*

#### - Inactive ingredients:

*Mannitol, Microcrystalline cellulose  
Hypromellose (Methocel K 100 M  
Premium CR/HPMC 2208),  
Hypromellose (Methocel K 15 M  
Premium CR/HPMC 2208),  
Pregelatinized corn starch, Yellow  
iron oxide (C.I. No. 77492),  
Povidone (PVP K-30), Purified  
water, Isopropyl alcohol,  
Colloidal silicon dioxide and  
Magnesium stearate*

### - MAL Number: -

**MAL**

## Manufacturer

UNISON LABORATORIES CO., LTD.  
39 Moo 4, Klong Udomcholjorn, Muang  
Chachoengsao, Chachoengsao 24000  
Thailand

## Product Registration Holder

Medispec (M) Sdn Bhd  
B-1-07, Jalan SS 25/22,  
Taman Mayang,  
47301 Petaling Jaya,  
Selangor, Malaysia

## Date of Revision

03.02.2026

## Serial number

NPRA (R2) 24/139