

# PENCOR 4 mg Tablet

Doxazosin (4 mg)

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## What PENCOR is used for

**Hypertension:** PENCOR is indicated for the treatment of hypertension and can be used as the sole agent to control blood pressure in the majority of patients. In patients inadequately controlled on single antihypertensive therapy, PENCOR may be used in combination with a thiazide diuretic, beta-adrenoceptor blocking agent, calcium antagonist or an angiotensin-converting enzyme inhibitor.

**Benign prostatic hyperplasia:** PENCOR is indicated for the treatment of urinary outflow obstruction and symptoms associated with benign prostatic hyperplasia (BPH). PENCOR may be used in BPH patients who are either hypertensive or normotensive.

## How PENCOR works

PENCOR works by relaxing blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

In patients with enlargement of the prostate gland, PENCOR is taken to treat frequent and/or poor passing of urine. This is common in patients with enlargement of the prostate gland. PENCOR works by relaxing muscle around the bladder exit and prostate gland so urine is passed more easily.

## Before you use PENCOR

### - When you must not use it

- ⊗ If you are allergic (hypersensitive) to Doxazosin or to other alpha-blocking agents/drugs (such as Terazosin or Prazosin).
- ⊗ If you are allergic (hypersensitive) to any of the other ingredients of PENCOR.
- ⊗ If you are Pregnant and breast-feeding
  - ⇒ The safety of using PENCOR during pregnancy has not been established. PENCOR may be used only if the doctor decides that the anticipated benefit of the treatment outweighs the potential risks to the fetus.

If you are planning to become pregnant or think that you may be pregnant, speak to your doctor to know if PENCOR is suitable for you.

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

Do not use this medicine if any of the above applies to you. If you are not sure, get advice from your doctor or pharmacist before taking PENCOR.

### - Before you start to use it

**Postural hypotension/ Syncope:** As with all alpha-blockers, a very small percentage of patients have experienced postural hypotension evidenced by dizziness and weakness, or rarely loss of consciousness (syncope), particular with the commencement of therapy.

When instituting therapy with any effective alpha-blocker, ask your doctor on how to avoid symptoms resulting from postural hypotension and what necessary measures to take in case it develops.

Take extra caution and avoid situations where injury could result, should dizziness or weakness occur during the initiation of PENCOR therapy.

**Use with PDE-5 Inhibitors:** Inform your physician if you are currently using drugs for erectile dysfunction (impotence). Concomitant administration of this drug with a PDE-5 inhibitor (eg. Sildenafil) should be used with caution as it may lower your blood pressure more than what is normal/ needed.

**Impaired liver function:** Inform your doctor if you have liver problem. As with any drug, PENCOR should be administered with caution to patients with evidence of impaired hepatic function.

### - Taking other medicines

Please inform your doctor or pharmacist if you are using or have recently used any other medicines. This includes medicines that you buy without prescription and herbal medicines. This is because PENCOR can affect the way some medicines work. Also some other medicines can affect the way PENCOR works.

In particular, tell your doctor or pharmacist if you are using any drug indicated for erectile dysfunction (PDE-5 inhibitors) e.g. Sildenafil (*Viagra*®). Concomitant intake of an alpha blocker and a PDE-5 inhibitor medicine may lead to symptomatic hypotension.

## How to use PENCOR

### - How much to use

Oral

### *Hypertension*

PENCOR is used in once daily regimen: the initial dose is 1 mg, to minimize the postural hypotension and/or syncope. Dosage may then be increased to 2 mg after an additional one or two weeks therapy and thereafter, if necessary to 4 mg. The majority of patients who respond to PENCOR will do so at a dose of 4 mg or less. Dosage can be further increased if necessary to 8 mg or the maximum recommended dose of 16 mg.

### *Benign prostatic hyperplasia*

The recommended initial dosage of PENCOR is 1 mg given once daily to minimize the potential for postural hypotension and/or syncope. Depending on the assessment of your doctor and with his prescription, dosage may then be increased to 2 mg and thereafter to 4 mg or up to the maximum recommended dose of 8 mg. The recommended interval between dose adjustment is 1-2 weeks. The usual recommended dose is 2-4 mg daily.

### *Children*

The safety and efficacy of PENCOR in children have not been established.

### *Elderly*

Normal adult dosage

### *Patients with kidney problem*

Normal adult dose is recommended since no change was seen on how the drug was absorbed, takes effect and eliminated from the body even in the presence of kidney problem. However, it should be noted that Doxazosin cannot be removed by hemodialysis.

### *Patients with liver problem*

Currently, there are only limited data about patients with liver impairment and on the effect of drugs known to have significant influence to liver function.

As with any drug, those who are diagnosed with impaired liver problem must take extra caution while using this medicine. If you notice any undesirable effect, discontinue using and consult your doctor.

Follow carefully all directions given to you by your doctor and pharmacist. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

### - When to use it

Use as directed by your doctor or pharmacist.

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## - How long to use it

Continue taking PENCOR for as long as your doctor recommends.

## - If you forget to use it

Consult your doctor or pharmacist on what should you do if you forget to use it.

If you miss a dose, give the next dose as soon as you remember, provided that you do not give more than the recommended dose in 24 hours. If it is almost time for your next dose, do not take the dose that you missed.

Do not take a double dose to make up for the missed one.

## - If you use too much (Overdose)

Taking too many tablets at once may make you unwell. The most likely manifestation of a possible overdose would be hypotension (low blood pressure). Once this symptom has been observed, patient must immediately lie down in a supine position (lying on your back with face up) with legs slightly elevated. Other symptomatic treatment and supportive measures may be required.

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

## **While you are using it**

### - Things you must do

- ✓ Take your medicine exactly as your doctor has prescribed.
- ✓ Inform all the doctors, dentists and pharmacists treating you that you are taking PENCOR
- ✓ Tell your doctor immediately if you become pregnant while taking this medication.

### - Things you must not do

- ⊗ Do not stop taking the medicine unless advised by your doctor.
- ⊗ Do not take any new medicine without consulting your doctor.
- ⊗ Do not give PENCOR to anyone else, even if they have the same symptoms or condition as you.
- ⊗ Activities requiring mental alertness: Do not drive or operate machine that requires mental alertness if you are scheduled to start this medication PENCOR may cause dizziness and syncope (loss of consciousness), particularly when taking your initial dose of this medicine.

## - Things to be careful of

If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately

## **Side effects**

As with all drugs, PENCOR is likely to have undesirable effects, although not everybody gets them.

*Side effects that indicate urgent need for medical attention:*

- Some patients may experience faintness or dizziness or light headedness, which may be caused by low blood pressure upon sitting or standing up quickly (postural hypotension). This is more common on patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement.
- Sensation that the surroundings are moving or spinning (vertigo)
- Irregular heartbeat (arrhythmias)
- Loss of consciousness (syncope)
- Shortness of breath (dyspnea)
- Pounding heartbeat (palpitations)
- Swelling of feet or lower legs (edema)
- Fast heartbeat (tachycardia)
- Prolonged, usually painful erection of the penis (Priapism)

*Side effects that indicate need for medical attention only if they continue or are bothersome:*

- Headache, unusual tiredness,
- Nausea, vomiting
- Nervousness, restlessness, or unusual irritability
- Runny nose (rhinitis)
- Sleepiness or unusual drowsiness (somnolence)

If any of the side effects happens, or if you notice any undesirable effects which have not been mentioned here, discontinue using this medication and consult your doctor / pharmacist or go to the nearest hospital immediately.

You may report any side effects or adverse drug reactions directly to the **National Centre for Adverse Drug Reaction Monitoring** by calling *Tel: 03-78835550*, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting)

## **Storage and Disposal of PENCOR**

### - Storage

Keep medicine out of reach of children. Store at temperature of not more than 30°C.

### - Disposal

Shelf – life: Three (3) years

Medicine 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, square, biconvex, tablet with engraved PENCOR 4 on one side and scored on the other

### - Ingredients

Active ingredient: Doxazosin mesylate

Inactive ingredients:

Lactose monohydrate, Microcrystalline cellulose, Croscarmellose sodium, Talc, Providone K-90, Polysorbate 80, Sodium lauryl sulfate, Colloidal silicon dioxide, Magnesium stearate, and Tapioca starch

**MAL. NO:** MAL06071055A

## **Manufacturer**

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

## **Product Registration Holder**

MEDISPEC (M) SDN. BHD  
# 55 & 57 Lorong Sempadan 2, (Off Boundary) 11400 Ayer Itam, Penang, Malaysia

## **Date of Revision**

25/09/2014

## **Serial Number:**

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