

# ATODEL TABLET 1MG

Prazosin Hydrochloride (1mg)

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## What Atodel is used for

Atodel is indicated for the treatment of hypertension (either used alone or in conjunction with a diuretic and/or other antihypertensive drugs), congestive cardiac failure and Raynaud's syndrome (reduced blood flow which cause discoloration of fingers, toes and other areas).

## How Atodel works

Prazosin the active ingredient of Atodel, is a vasodilator, an antihypertensive drug which belongs to the group of medicines known as alpha-blockers. Prazosin works by relaxing blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

In heart failure, the treatment works by relaxing the main blood vessels of the heart, allowing the heart to pump blood more easily.

In patients with Raynaud's disease the treatment relaxes blood vessels of the hands, so blood can reach fingers more easily. This helps to prevent coldness and stiffness.

## Before you use Atodel

### - When you must not use it

Atodel is contra-indicated in patients with sensitivity to Prazosin or any other ingredient of the product, in patients with congestive heart failure due to mechanical obstruction such as aortic valve stenosis, mitral valve stenosis, pulmonary embolism and restrictive pericardial disease.

It is also contra-indicated in children under the age of 12 years.

### - Special Warnings

*In patients with congestive cardiac failure:* Atodel is not recommended in the treatment of congestive cardiac failure due to mechanical obstruction such as aortic valve stenosis, mitral valve stenosis, pulmonary embolism and restrictive pericardial disease.

*In patients with hypertension:* A very small percentage of patients may respond in an abrupt and exaggerated manner to the initial dose of Atodel.

*Raynaud's phenomenon and Raynaud's disease:* because Prazosin decreases peripheral vascular resistance, careful monitoring of blood pressure during initial administration and during subsequent dosage increments of Atodel is suggested.

Atodel contain lactose, therefore if you have been told by your doctor that you have intolerance to some sugars, consult your doctor before taking this medicinal product.

Atodel contains Sunset Yellow E110 which may cause allergic reactions.

### - Pregnancy

Studies to date are inadequate to establish the safety of Prazosin in pregnancy. Therefore, the medicine may be used only if in the opinion of the physician, potential benefit to the mother outweighs the potential risk to the foetus. Consult your doctor before you take any medicine.

### - Lactation

Prazosin is excreted in small amounts in human milk.

Caution should be exercised when Prazosin is administered to nursing mothers.

### - Before you start use it

You must tell your doctor if you are:

- if you are hypersensitive (allergic) to prazosin or to any of the ingredients of the product.
- if you have renal or liver failure.

- if you are pregnant or you intend to become pregnant.
- if you are breast-feeding.

### - Taking other medicines

You must tell your doctor if you are taking any other medicines, including any that you buy without a prescription.

There is evidence that adding Prazosin to beta-adrenergic antagonist or calcium antagonist therapy may produce a substantial reduction in blood pressure.

Some patients who take alpha-blocker therapy for the treatment of high blood pressure may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly.

## How to use Atodel

### - How much to use

Follow all directions given to you by your doctor and pharmacist carefully. 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.

Adults:

*Patient with hypertension:* the dosage ranges from 0.5 mg – 20 mg daily. The therapy should be initiated with 0.5 mg two - three times daily for 3 – 7 days, with the first dose administered in the evening. The dose can be increased to 1 mg two - three times daily for another 3 – 7 days. Thereafter, the dose should be gradually increase, according to the patient's response to the blood pressure lowering effect. Maximum dose 20 mg daily in divided doses.

*Patients receiving other antihypertensive therapy but with inadequate control:* the dosage of the other drug should be reduced and Atodel initiated at 0.5 mg in the evening, then continuing with 0.5 mg two or three times daily. Subsequent dosage increase should be made gradually depending upon the patient's response.

*Patients with congestive heart failure:* the recommended starting dose is 0.5 mg two, three or four times daily, increasing

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to 4 mg in divided doses. The dosage should be titrated according to the patient's response and under close medical supervision. The usual daily maintenance dosage is 4 mg to 20 mg in divided doses.

*Patients with Raynaud's disease:* the recommended starting dose is 0.5 mg two times daily for 3 - 7 days. The dose thereafter is adjusted according to the patient's response. The usual maintenance dosage is 1 mg or 2 mg two times daily.

*Patients with impaired renal function:* the recommended starting dose is 0.5 mg daily and the dosage should be increased cautiously.

Children:

Atodel is not recommended for the treatment of children under the age of 12 years since safe conditions for its use have not been established.

Elderly:

Since the elderly may be more susceptible to hypotension, therapy should be initiated with the lowest possible dose.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Atodel for as long as your doctor recommends.

- If you forget to use it

If you have to take this medicine continuously and you missed a dose, take the missed dose as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Consult your doctor in case you missed more than one dose.

- If you use too much (overdose)

If you take a dose larger than normal stop taking the medicine and contact your doctor immediately. Do this even if there are no signs of discomfort or

poisoning. You may need urgent medical attention. Your doctor will decide the most suitable treatment for you.

**While you are using it**

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Atodel.
- Tell your doctor immediately if you become pregnant while taking this medication.
- Consult your doctor or pharmacist first before taking any other medication.
- In case of overdose contact your doctor immediately.
- Keep this leaflet in a safe place. You may need to read it again.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- This medicine was prescribed for you personally and you should not pass it on to others. It can be harmful, even if they have the same symptoms or condition as you.

- Things to be careful of

During driving or operating machinery, the patient must be cautioned to avoid situations where injury could result from dizziness or weakness occur during the initiation of Prazosin therapy.

**Side Effects**

As with all medicines, Atodel can cause undesirable effects. Please inform your doctor in case you noticed any of the following side effects.

Marked orthostatic hypotension (a fall in blood pressure on standing up which cause dizziness, light-headedness or fainting) and fainting, occasionally leading to sudden collapse or loss of consciousness, may occur at the onset of treatment. Side effects commonly include nasal congestion, dryness of the mouth, diarrhoea, depression, drowsiness,

postural hypotension, headache, lethargy, nausea, nervousness, oedema, chest pain and palpitations.

Constipation, dyspnoea (breathing difficulty), urinary frequency, blurred vision, tingling and numbness, reddened sclera (eye white), tinnitus, skin rashes, itchiness, diaphoresis (excessive sweating), fainting, tachycardia (faster heart beat), impotence and vomiting may occur. Paroxysmal tachycardia and vivid dreams have occurred in association with Atodel.

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

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 Atodel**

- Storage

Keep below 25°C, protected from light and moisture and in safe place away from the reach and sight of children.

Product expiry date is shown on the inner and outer packaging. In case the expiry date has lapse, do not use.

- 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

Orange, round, N.C scored tablets with Remedica's logo on one side.

- Ingredients

Active ingredient(s): Prazosin Hydrochloride  
Inactive ingredients: Povidone, Lactose, Microcrystalline Cellulose, Maize

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Consumer Medication Information Leaflet (RiMUP)

Prazosin Hydrochloride (1mg)

Starch, Croscarmellose Sodium, Sodium  
Starch Glycolate, Colloidal Silicon  
Dioxide, Magnesium Stearate, Talc,  
Sunset Yellow E110

- MAL number(s):

MAL19940736A

## **Manufacturer**

Remedica Ltd., Limassol Industrial  
Estate, Limassol, Cyprus, EU.

## **Product Registration Holder**

LF Asia (Malaysia) Sdn Bhd (719-V)  
Lot 6, Persiaran Perusahaan, Seksyen 23,  
40300 Shah Alam,  
Selangor Darul Malaysia

## **Date of Revision**

22/01/2014