MINIPRESS® TABLET

Prazosin Hydrochloride (1 mg, 2 mg & 5 mg)

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What is in this leaflet?

What MINIPRESS is used for

MINIPRESS is one of a group of medicines called alpha-blockers.

It is usually used to treat high blood pressure (hypertension). It may also be used to treat heart failure (left ventricle-related), painful cold fingers (Raynaud's Disease) or mild enlargement of the prostate gland (Benign prostatic hyperplasia) in men.

How MINIPRESS works

In patients with high blood pressure (hypertension) MINIPRESS works by relaxing blood vessels (more on peripheral vessels) so that blood passes through them more easily. It can be used alone or in combination with other drugs used to treat hypertension.

In patients with heart failure, MINIPRESS works by relaxing the main blood vessels of the heart, allowing the heart to pump blood more easily. MINIPRESS is usually used in heart failure when other drugs are either no longer working or have not worked at all.

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

In patients with Benign Prostatic Hyperplasia, enlargement of the prostate gland, the medicine is taken to treat the poor and/or frequent passing of urine. This is common in patients with enlargement of the prostate gland. The treatment works by relaxing muscle around the bladder and prostate gland so urine can pass through easily.

You should ask your doctor if you are unsure why you have been given MINIPRESS.

Before you use MINIPRESS

- *When you must not use it*

Do not take MINIPRESS if you:

- are allergic (hypersensitive) to prazosin, or to any similar drugs (known as quinazoline drugs) or any of the other ingredients listed under Product Description. This may cause itching, reddening of the skin or difficulty in breathing.
- are under 12 years of age.

Pregnancy and lactation

If you are pregnant, planning to get pregnant or are breast-feeding, tell your doctor before you take MINIPRESS.

MINIPRESS should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and fetus.

MINIPRESS has been shown to be excreted in small amounts in human milk. Caution should be exercised when Minipress is administered to nursing mothers.

Ask your doctor or pharmacist for advice before taking any medicine.

- *Before you start to use it*

Talk to your doctor or pharmacist regarding these before taking MINIPRESS.

Medicines are not always suitable for everyone. Your doctor needs to know before you take MINIPRESS if any of the following apply to you:

- You have heart failure because of another heart condition, e.g. heart valve disease, or a recent heart attack. If you have heart failure, left ventricle-related) MINIPRESS can gradually become less helpful over several months. If this happens you may notice swelling of your legs or ankles due to retention of fluid called 'oedema'. If you develop weight gain from oedema tell your doctor as he/she may need to change the dose of MINIPRESS or other medicines you are taking.
- You have ever fainted after passing urine.
- You have liver or kidney disease.
- Remember to tell your doctor that you are taking MINIPRESS if you have any tests, such as a urine analysis, as MINIPRESS may affect its result.
- Some patients who take MINIPRESS for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking drugs for erectile dysfunction (impotence) with MINIPRESS. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of MINIPRESS before you start drugs for erectile dysfunction.
- you have prolonged erection of the penis. If erection persists longer than 4 hours, seek immediate medical help.

- *Taking other medicines*

Some medicines can affect the way MINIPRESS works. If you are taking any of the following medicines tell your doctor before you start the treatment:

- calcium antagonists, ACE inhibitors or beta-blockers which are usually given to treat angina and/or high blood pressure
- medicines for erectile dysfunction (impotence).
- use with PDE-5 inhibitors
- cardiac glycosides: digitals and digoxin
- hypoglycemic agents: insulin, chlorpropamide, phenformin, tolazamide, and tolbutamide
- tranquilizers and sedatives: chlordiazepoxide, diazepam, and phenobarbital

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- agents for the treatment of gout: allopurinol, colchicine, and probenecid
- antiarrhythmic agents: procainamide, propranolol and quinidine
- analgesics, antipyretics and anti-inflammatory agents: propoxyphene, aspirin, indomethacin, and phenylbutazone type

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

How to use MINIPRESS

- *How much to use*

Always take MINIPRESS exactly as prescribed by your doctor. You should check with your doctor or pharmacist if you are not sure.

MINIPRESS tablets are to be taken by mouth. MINIPRESS can be taken before or aftermeals.

MINIPRESS is usually started at the lowest possible dose and gradually increased, depending on how you respond to treatment. Do not change the dose or stop taking the tablets without first checking with your doctor. Make sure you get a new prescription before your tablets run out.

High blood pressure (hypertension) –
The recommended starting dose is 0.5 mg once at bedtime. Then 0.5 mg is given, two or three times a day for 3 to 7 days.

The dose is usually then increased to 1 mg taken two or three times a day for a further 3 to 7 days. Your doctor may then advise you to gradually increase the dose further (up to a maximum of 20 mg daily) depending on how your blood pressure has responded to treatment.

If you are taking any diuretics or any other medicines for high pressure but your blood pressure is not controlled with it, your doctor will reduce the dosage for the particular agent to a maintenance level before starting MINIPRESS treatment.

Heart failure (Left Ventricle-Related)
The recommended starting dose is 0.5 mg taken two, three or four times a day. Your doctor may then advise you to increase the dose further (up to a maximum of 20 mg daily) depending on how you have responded to treatment.

Raynaud's Phenomenon/Disease
The recommended starting dose is 0.5 mg, twice a day for 3 to 7 days. Your doctor may then advise you to increase the dose further (up to 2 mg twice a day) depending on how you have responded to treatment.

Enlarged prostate
The recommended starting dose is 0.5 mg, twice a day for 3 to 7 days, with the initial dose taken in the evening. Your doctor may then advise you to increase the dose further (up to 2 mg twice a day) depending on how you have responded to treatment.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue taking MINIPRESS for as long as your doctor recommends.

- *If you forget to use it*

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose.
Do not take a double dose to make up for a missed dose.

- *If you use too much (overdose)*

If you accidentally take too much MINIPRESS, contact your doctor immediately or go to your nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any MINIPRESS left or not.

- *If you stop taking it*

Do not stop taking MINIPRESS unless your doctor tells you to. Your condition may return if you stop using MINIPRESS.

If you have any further questions on how to take this product, ask your doctor or pharmacist.

While you are using it

- *Things you must do*

Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist.

- *Things you must not do*

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.

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

- *Things to be careful of*

Driving and using machines

MINIPRESS may cause dizziness, drowsiness or weakness. If you experience these symptoms, do not operate any motor vehicle or use any tools.

Side effects

MINIPRESS like most medicines may cause side effects, but not everybody gets them.

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

The most common reactions associated with MINIPRESS therapy are:

Lack of energy, weakness, dizziness headache, nausea, unpleasant sensation of forceful beating of the heart, drowsiness.

In most instances side effects have disappeared with continued therapy or

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have been tolerated with no decrease in dosage of the drug.

In addition, the following reactions have been associated with prazosin hydrochloride therapy:

Excessive sweating, dry mouth, flushing, persistent erection of penis, allergic reaction, weakness, fever, illness, pain, chest pain, swelling of the feet, ankles or legs, low blood pressure, drop in blood pressure due to change in body position, fainting, tingling/numb sensation of arms and feet, spinning dizziness, presence of antinuclear antibodies, abnormal breast tissue development, especially in men abdominal discomfort and/or pain, constipation, diarrhea, inflammation in the pancreas, vomiting, ringing in the ears, abnormal slow heart rate, abnormal rapid heart rate, liver function abnormalities, joint pain, depression, hallucinations, impotence, inability to sleep, nervousness, shortness of breath, nosebleed, nasal congestion, hair loss, itchy skin, rash, lichen planus , hives, inability to control urination, urinary frequency, inflammation of blood vessels, blurred vision, inflammation of the white outer surface of the eye, eye pain.

Some of these reactions have occurred rarely, and in many instances the exact causal relationships have not been established.

Literature reports exist associating prazosin hydrochloride therapy with a worsening of pre-existing narcolepsy. A causal relationship is uncertain in these cases.

The following have been observed in patients being managed for left ventricular failure with prazosin hydrochloride when used in conjunction with cardiac glycosides and diuretics:

Dry mouth, swelling, drop in blood pressure due to change in body position, dizziness, headache, diarrhea, nausea, abnormal heart beat, drowsiness, impotence, nasal congestion, blurred vision.

In most instances these occurrences have been mild to moderate in severity and have resolved with continued therapy or have been tolerated with no decrease in drug dosage.

The most commonly although infrequently reported side effect in the treatment of Raynaud's Phenomenon/Disease was mild dizziness.

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 [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of MINIPRESS

- *Storage*

  Keep out of the reach and sight of children.

  Do not use MINIPRESS after the expiry date which is stamped on the pack after EXP. The expiry date refers to the last day of that month.

  Store below 30°C.

- *Disposal*

  Medicines should not be disposed of via wastewater of 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*

  MINIPRESS 1 mg: Orange, round, biconvex tablet with 'K' breakline 'K' on one side and Pfizer logo on the other.

  MINIPRESS 2 mg: White, round, biconvex tablet with 'K' breakline 'K' on one side and Pfizer logo on the other.

  MINIPRESS 5 mg: White, diamond shaped tablet with 'K' breakline 'K' on one side and 'MNP' breakline '5' on the other.

- *Ingredients*
  - Active ingredient
    Each prazosin hydrochloride tablet contains the equivalent of 1, 2, 5 mg of prazosin free base.

  - Inactive ingredients
    1 mg tablet
    Microcrystalline cellulose, FD and C Yellow No 6 Lake, dibasic calcium phosphate, maize starch, magnesium stearate, sodium lauryl sulphate.

    2 mg tablet
    Microcrystalline cellulose, dibasic calcium phosphate, maize starch, magnesium stearate, sodium lauryl sulphate.

    5 mg tablet
    Microcrystalline cellulose, dibasic calcium phosphate, maize starch, magnesium stearate, sodium lauryl sulphate

- *MAL numbers:*

Product Name	Registration Number
MINIPRESS 1 mg	MAL19930148ACSZ
MINIPRESS 2 mg	MAL19930149ACSZ
MINIPRESS 5 mg	MAL19930150ACSZ

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