

T.O. PRAZOSIN TABLET

Prazosin Hydrochloride (1 mg, 2 mg)

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What T.O. Prazosin is used for

T.O. Prazosin is usually used to treat high blood pressure (hypertension).

It may also be used to treat heart failure (left ventricle-related), Raynaud's disease (where the fingers become white and painful when cold) or enlargement of the prostate gland (benign prostatic hyperplasia) in men.

When used to treat high blood pressure or heart failure, T.O. Prazosin is often used in combination with other medicines.

How T.O. Prazosin works

T.O. Prazosin contains the active substance Prazosin Hydrochloride, which is one of a group of medicines called alpha-blockers.

In patients with high blood pressure (hypertension), T.O. Prazosin works by relaxing blood 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, T.O. Prazosin works by relaxing the main blood vessels of the heart, allowing the heart to pump blood more easily. T.O. Prazosin 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 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 is passed more easily.

Before you use T.O. Prazosin

- When you must not use it

Do not take this medicine if:

- you are allergic (hypersensitive) to Prazosin Hydrochloride or to any similar drugs (known as quinazoline drugs) or any of the other ingredients listed under Product Description.
- you are under 12-years of age

- Before you start to use it

Check with your doctor or pharmacist before taking T.O. Prazosin.

Medicines are not always suitable for everyone. Your doctor needs to know before you take T.O. Prazosin 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), T.O. Prazosin 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 T.O. Prazosin or other medicines you are taking.
- you have ever fainted after passing urine.
- you have liver or kidney disease.
- you have prolonged erection of the penis. If erection persists longer than 4 hours, seek immediate medical help.

Remember to tell your doctor that you are taking T.O. Prazosin if you have any tests, such as a urine analysis, as T.O. Prazosin may affect its result.

Some patients who take T.O. Prazosin for the treatment of high blood pressure or prostate enlargement may experience dizziness or lightheadedness, 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 T.O. Prazosin. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of T.O. Prazosin before you start drugs for erectile dysfunction.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before you take T.O. Prazosin.

T.O. Prazosin should be used during pregnancy only if the potential benefit justifies the potential risk to the mother and foetus.

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

- Taking other medicines

Tell your doctor if you are taking any other medicines, or have recently taken any. This includes medicines bought without a prescription from a pharmacy, supermarket or health food shop.

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

- diuretic tablet, also known as "water tablet" such as frusemide.
- 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.

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How to use T.O. Prazosin

- How much to use

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

T.O. Prazosin tablets are to be taken by mouth. T.O. Prazosin can be taken before or after meals. Swallow the tablets with a glass of water.

T.O. Prazosin 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 T.O. Prazosin 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 T.O. Prazosin for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor or pharmacist for advice or go to the Emergency Department of your nearest hospital, if you take too many T.O. Prazosin tablet. Always take the labelled medicine package with you, whether there is any T.O. Prazosin left or not.

While you are using T.O. Prazosin

- Things you must do

- Always follow the instructions given by your doctor.
- Inform your doctor immediately if you become pregnant while taking this medication.
- You may feel dizzy, light-headed, or faint, especially when you first start taking T.O. Prazosin or after your dose is increased. If you experience dizziness, light-headedness, or fainting, rise slowly when getting out of bed or standing up. Inform your doctor if these symptoms persist.
- If you are about to start any new medication, remind your doctor or pharmacist that you are taking T.O.

Prazosin.

- Inform all doctors, dentists, and pharmacists treating you that you are currently taking T.O. Prazosin.

- Things you must not do

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

Do not use T.O. Prazosin to treat other health problems unless directed by your doctor.

Do not take any new medicines without consulting your doctor.

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.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or operate machinery. If it causes nausea, dizziness, fatigue, or headache, do not drive or operate machinery and contact your doctor immediately.

Side effects

Like all medicines, T.O. Prazosin can cause side effects although not everybody gets them.

The most common reactions associated with T.O. Prazosin therapy are:

- lack of energy
- weakness
- dizziness
- headache
- nausea
- unpleasant sensation of forceful beating of the heart
- drowsiness

In addition, the following reactions have been associated with Prazosin Hydrochloride therapy:

- persistent erection of penis
- chest pain
- fainting
- abnormal breast tissue development, especially in men
- shortness of breath
- nosebleed

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- blurred vision
- inflammation of the white outer surface of the eye
- joint pain
- abdominal discomfort and/or pain

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

The most commonly although infrequently reported side effect in the treatment of Raynaud's Phenomenon/Disease:

- mild dizziness

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

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

Storage and disposal of T.O Prazosin

- Storage

Do not store above 30°C.

Store the medicine in its original packaging to protect it from heat, moisture, and light.

Do not store T.O. Prazosin or other medicines in the bathroom, near the sink, or leave them by the window or in the car.

Keep out of the reach and sight of children

- Disposal

Medicines should not be disposed 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

T.O. Prazosin 1 mg: Orange, round, biconvex tablet with a breakline on one side.

T.O. Prazosin 2 mg: White, round, biconvex tablet with a breakline and a figure "2" on one side and letters "TOC" on the other.

- Ingredients

- Active ingredient

T.O. Prazosin 1 mg: Each tablet contains 1.095 mg of Prazosin hydrochloride, equivalent to 1 mg of Prazosin

T.O. Prazosin 2 mg: Each tablet contains 2.190 mg of Prazosin hydrochloride, equivalent to 2 mg of Prazosin.

- Inactive ingredients

Lactose, corn starch, povidone K-90, sodium starch glycolate, talcum, magnesium stearate, polysorbate 80.

T.O. Prazosin 1 mg also contains "sunset yellow" as a coloring agent.

- MAL number

T.O. Prazosin 1mg
(MAL04112728ARZ)

T.O. Prazosin 2mg
(MAL04112729ARZ)

Manufacturers

- Packed and released by

GoodScience Sdn. Bhd.
No. 7, Jalan KPK 4/3,
Kawasan Perindustrian Kundang,
Kundang Jaya, 48020 Rawang,
Selangor, Malaysia.

- Manufactured by
T.O PHARMA CO., LTD.
120, Lat Phrao 128 Alley,
Khaeng Phlabphla,
Khet Wang Thonglang,
Bangkok 10312, Thailand.

Product Registration Holder

GoodScience Sdn. Bhd.
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