

**Terazosin**  
**2 mg, 5 mg and 10 mg Tablets**  
terazosin hydrochloride dihydrate

**Package leaflet:**  
**Information for the user**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet:**

1. **What Terazosin Tablets are and what they are used for**
2. **What you need to know before you take Terazosin Tablets**
3. **How to take Terazosin Tablets**
4. **Possible side effects**
5. **How to store Terazosin Tablets**
6. **Contents of the pack and other information**

**1 What Terazosin Tablets are and what they are used for**

The name of your medicine is Terazosin 2 mg, 5 mg, or 10mg Tablets. Terazosin belongs to a group of medicines called alpha-blockers.

Terazosin Tablets are used to treat:

- high blood pressure
- blocked urine flow caused by benign prostatic hyperplasia (BPH), which is common in older men.  
BPH is caused by the prostate gland growing too big and obstructing the flow of urine from the bladder. This leads to some unpleasant symptoms such as weak or interrupted urine flow, a need to pass water more frequently and/or a sudden need to pass water. Terazosin Tablets can relax the muscle of the prostate gland and bladder exit to help relieve these symptoms.

**2 What you need to know before you take Terazosin Tablets**

**Do not take Terazosin Tablets if you:**

- are allergic (hypersensitive) to terazosin or any of the other ingredients of this medicine listed in section 6 (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing).
- are allergic (hypersensitive) to other alpha-adrenoceptor blockers, other similar medicines such as alfuzosin, indoramin, prazosin, tamsulosin, doxazosin
- have ever fallen over or fainted while passing water
- have the rare hereditary problem of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption.

**Warnings and precautions**

**Talk to your doctor or pharmacist before taking Terazosin Tablets if you:**

- are taking other medication for high blood pressure. If a medicine for high blood pressure is started whilst you are taking Terazosin Tablets, then your doctor may need to adjust your dose of Terazosin Tablets.
- have any heart problems
- are taking medicines for erectile dysfunction (e.g. Cialis, Viagra, Levitra, Stendra)
- are planning cataract removal surgery.

**Terazosin Tablets must be used for BPH only after excluding other possible reasons in urinary tract for abnormal/interrupted urinary flow.**

**Terazosin Tablets can cause fainting or low blood pressure, usually after the first or first few doses. These effects can also occur if you stop taking Terazosin Tablets and then re-start.**

**Terazosin Tablets may also lead to decreases of certain laboratory values, such as red blood cells or white blood cells.**

**If any of the above applies to you, or if you are not sure, please tell your doctor before taking Terazosin Tablets.**

**Children and adolescents**

Terazosin Tablets are not recommended for use in children.

**Other medicines and Terazosin Tablets**

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

It is especially important to tell your doctor if you are taking,

- ACE inhibitors, used to treat high blood pressure e.g. captopril or lisinopril
- diuretics ("water tablets"), used to treat heart failure or high blood pressure e.g. furosemide or spironolactone
- any other medicine used to treat high blood pressure e.g. atenolol, verapamil or amlodipine

- medicines for erectile dysfunction (e.g. Cialis, Viagra, Levitra, Stendra).

Some patients who take alpha-blocker therapy 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.

**The medicines which cause low blood pressure with alpha-blockers include:**

- medicines treating high blood pressure - adrenergic neurone blockers (e.g. Guanethidine)
- alcohol
- cancer treating medicine (e.g. aldesleukin)
- medicines for treating high blood pressure (e.g. Angiotensin –II receptor antagonists, Beta blockers, Calcium-channel blockers, Clonidine, Moxinidine, Tizanidine, Diazoxide, Hydralazine, Nitrates, Sodium nitroprusside)
- medicines for treating schizophrenia (antipsychotics)
- medicines for treating muscle spasm (e.g. baclofen)
- anti-inflammatory drugs like corticosteroids
- medicines used for general anaesthesia before surgery
- medicine used for baldness (Minoxidil)
- medicines for treating Parkinson's condition (e.g. levodopa and Methyldopa)
- medicines for treating depression (MAO's).

Certain patients have experienced these symptoms when taking drugs for erectile dysfunction (impotence) with alpha-blockers. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start drugs for erectile dysfunction.

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

If you are going to have a general anaesthetic, you should tell the doctor or dentist in charge that you are taking Terazosin Tablets.

If you are undergoing eye surgery because of cataract (cloudiness of the lens), please inform your eye specialist before the operation that you are using or have previously used Terazosin Tablets. This is because terazosin may cause complications during the surgery which can be managed if your specialist is prepared in advance.

**Pregnancy and breast-feeding**

If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine.

**Pregnancy**

Terazosin Tablets should not be used during pregnancy unless considered appropriate by your doctor.

**Driving and using machines**

- Terazosin Tablets may cause light-headedness, dizziness, or drowsiness, particularly with the first dose, an increase in your dose, or after missing doses and restarting treatment. DO NOT drive or operate machinery for 12 hours after your first dose, when your dose is increased, or when restarting treatment.
- If you are affected in any way at any other time while you are taking Terazosin Tablets, DO NOT drive or operate machinery.

**Terazosin Tablets contain lactose**

- Patients who are intolerant to **lactose** should note that Terazosin Tablets contain a small amount of lactose. If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**3 How to use Terazosin Tablets**

Always take Terazosin Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will monitor you regularly during your treatment.

**(A) Read this section if you are taking**

**Terazosin Tablets for the first time or if you have not taken Terazosin Tablets in the last week.**

**If you are continuing treatment without a break, please read section (B).**

**It is important that you take the correct tablet at the correct time.**

- The tablets should be swallowed, preferably with a drink of water.
- The first time you take a new strength of Terazosin Tablet, you should take it in the evening at bedtime.
- Following doses of the same strength may be taken in the morning.
- If you are at all unsure about when to take your tablets, you should consult your doctor for advice.

**Adults (including the elderly)**

**• High Blood Pressure**

On days 1 to 7, take one 1 mg tablet each day. The first tablet should be taken at bedtime.

From day 8 onwards, take one 2 mg tablet (yellow tablet) each day for a week, until you reach day 14.

Remember you should take your first 2 mg tablet at bedtime.  
When you have finished this two-week treatment, your doctor will decide how to continue your treatment, and may give you a prescription for more tablets. Now read section (B).

- **Benign prostatic hyperplasia**  
On days 1 to 7, take one 1 mg tablet each day. The first tablet should be taken at bedtime.  
From day 8 onwards, start taking one 2 mg tablet (yellow tablet) each day for 14 days. Remember you should take your first 2 mg tablet at bedtime.  
From day 22 onwards, start taking one 5 mg tablet (tan tablets) each day for 7 days. Remember you should take your first 5 mg tablet at bedtime.  
When you have finished this four-week treatment, your doctor will decide how to continue your treatment, and may give you a prescription for more tablets. Now read section (B).

**(B) Read this section if you have taken Terazosin Tablets before and are continuing with your next pack.**

- When you have finished your last pack, your doctor may prescribe more tablets to continue your treatment. Your maintenance dose will be adjusted according to how you have responded to treatment and is usually between 2 – 10 mg daily. Your doctor will decide which strength of tablet you need. You may be given a new pack of tablets containing either 2 mg (yellow tablets), 5 mg (tan tablets) or 10 mg (blue tablets) of terazosin.

**Take one tablet each day.**

**Use in Children**

- Terazosin Tablets are not recommended for use in children.

**If you take more Terazosin Tablets than you should**

- If you accidentally take more than 1 tablet in a day, you should contact your doctor immediately.
- If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital emergency department or your doctor immediately. An overdose is likely to cause very low blood pressure resulting in fainting, dizziness, and drowsiness. Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

**If you forget to take Terazosin Tablets**

- If you have forgotten to take a tablet of a new strength at bedtime, ask your doctor or pharmacist for advice before continuing.
- If you forget to take a tablet at the normal time, take one as soon as you remember. DO NOT take a double dose to make up for a forgotten dose. Take the remaining doses at the correct time.
- If you have forgotten to take a tablet for several days, DO NOT continue using the same tablets. **You must contact your doctor for advice before you start taking Terazosin Tablets again as your treatment may have to be restarted as if you are taking it for the first time.**

**If you stop taking Terazosin Tablets**

- You should continue to take your tablets unless your doctor tells you not to. DO NOT stop just because you feel better.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4 Possible side effects**

Like all medicines, Terazosin Tablets can cause side effects, although not everybody gets them.

If the following happens, stop taking the tablets and tell your doctor immediately or go to the emergency department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

When you first start taking the tablets or when you start to take a higher dose, dizziness, light-headedness or fainting may occur. These effects may also occur when standing up quickly from a lying or sitting position. If this happens you should lie down until you feel better, then you should sit for a few minutes before standing again to prevent these effects from returning.

These effects usually go away and should not return once you have become used to taking your tablets.

**Not known: (frequency cannot be estimated from the available data)**

- low blood platelet count
- weakness, dizziness
- a fast or uneven heartbeat
- feeling sick
- swelling of the hands and feet

- asthenia (decrease in muscle strength)
- sleepiness
- blocked nose
- blurred vision
- back pain, neck pain, shoulder pain
- pains in hands and feet, pins and needles
- headache
- low blood pressure (hypotension) which can cause dizziness or faintness on standing
- loss of consciousness
- dilatation of blood vessels
- weight gain
- nervousness, depression, anxiety
- shortness of breath or difficulty breathing
- decreased sex-drive, erectile dysfunction, persistent and painful erection
- vertigo (problems with balance that can result in feelings of dizziness or sickness – particularly on standing)
- chest pains
- facial swelling, flushing
- stomach pain, indigestion
- being sick, constipation, diarrhoea, passing wind (flatulence)
- dry mouth
- inflammation or pains in joints or muscles
- difficulty sleeping
- bronchitis (inflammation of the lungs)
- sinusitis (inflammation of nasal passage)
- rhinitis (Irritation and swelling of the mucous membrane in the nose)
- nose bleeds
- flu-like symptoms, pain and irritation of the throat, sore throat, cough
- skin rashes and itching
- sweating
- vision problems and conjunctivitis
- ringing in the ears; increased frequency of passing water, urinary infection, lack of bladder control
- low blood cell counts, laboratory tests abnormal.

Some patients have experienced unexpected bruising and their blood taking longer than usual to clot after a cut to the skin.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

**5 How to store Terazosin TABLETS**

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package. Do not use Terazosin Tablets after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**6 Contents of the pack and other information**

**What Terazosin Tablets contain:**

- The active ingredient is 2 mg, 5 mg or 10 mg terazosin as hydrochloride dihydrate.
- The other ingredients are lactose monohydrate, maize starch, povidone, crospovidone, talc and magnesium stearate (E572).
- The 2 mg tablets also contain quinoline yellow (E104).
- The 5 mg tablets also contain yellow iron oxide (E172) and red iron oxide (E172).
- The 10 mg tablets also contain indigo carmine (E132).

**What Terazosin Tablets look like and contents of the pack:**

- The 2 mg tablets are mottled yellow, round, flat tablet with bevelled edges. Embossed with “93” on one side and “761” on the other side. Available in packs of 20, 28, 30, 50, 84, and 100 tablets.
- The 5 mg tablets are mottled tan, round, flat tablet with bevelled edges. Embossed with “93” on one side and “762” on the other side. Available in packs of 14, 20, 28, 30, 50, 84, and 100 tablets.
- The 10 mg tablets are mottled blue, round, flat tablet with bevelled edges. Embossed with “93” on one side and “763” on the other side. Available in packs of 20, 28, 50, 84, and 100 tablets.
- The 2 mg and 5 mg tablets also come in starter packs.  
Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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