

Terazosin 5mg Tablets

(terazosin)

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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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
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1 What Terazosin Tablets are and what they are used for

Terazosin belongs to the class of drugs known as alpha-1- selective adrenoreceptor blocking agents.

Terazosin Tablets are used to:

- * treat mild to moderate high blood pressure (hypertension)
- * treat a condition called benign prostatic hyperplasia (BPH). This condition is caused by overgrowth of the prostate gland and is common in older men. When the prostate gland grows too big, it can partially block the flow of urine out of the bladder. This leads to symptoms such as:
 - * a weak or intermittent flow of urine
 - * a need to pass water more frequently or at night
 - * a sudden need to pass water.

2 What you need to know before you take Terazosin Tablets

Do not take Terazosin Tablets:

- * If you are allergic (hypersensitive) to the active ingredient, terazosin, to other quinazolines (e.g. prazosin, doxazosin alfuzosin, indoramin or tamsulosin) or to any of the excipients.
- * If you have ever experienced a brief loss of consciousness when passing water, or just after passing water. This symptom happens more commonly if you get up during the night to pass water.

Warning and precautions

Please tell your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses.

- * Fainting, unsteadiness or vertigo (a sensation of spinning around) caused by low blood pressure on standing up. It is more common:
 - * when you first start treatment
 - * when you restart treatment after a few days break
 - * if your body does not have enough fluids
 - * if you are on a low-salt diet
 - * in elderly people (over 65 years of age)

You may be more likely to experience fainting on standing if:

- * your dose of Terazosin is increased rapidly
- * you are also taking a diuretic (water tablet) or other medicine to help reduce your blood pressure.

You may notice that you have a rapid heartbeat just before fainting. The risk of fainting is greatest between 30 and 90 minutes after having taken your dose of Terazosin.

- * Hypotension (low blood pressure). Your doctor will monitor your blood pressure.
- * Heart problems such as water in the lungs or heart failure
- * Impaired liver function
- * Advanced kidney failure that requires intensive treatment or dialysis
- * Absence of urine production or decrease of the flow of urine
- * Upper urinary tract obstruction (when it is difficult for the urine to flow from the kidneys to the bladder)
- * Persistent infection of the urinary tract (an infection that could not been cured by treatment)
- * Bladder stones

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. This is because Terazosin may cause complications during the surgery, which can be managed if your specialist is prepared in advance.

Other medicines and Terazosin Tablets

If you are taking more than one medicine, there is always a risk that the medicines interfere with each other. Therefore, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

It is especially important for your doctor to know if you are already taking any of the following:

- * Other medicines used in the treatment of high blood pressure (other antihypertensive agents or other alpha-receptor blockers)
- * Clonidine (administered intravenously)
- * Nitrates used to treat heart pain (angina)
- * Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen or diclofenac, used as an antirheumatic or pain reliever
- * Oestrogens (female hormones, e.g. used in contraceptives)
- * Medicines including any of the following substances: dopamine, ephedrine, adrenaline, metaraminol, methoxamine, phenylephrine
- * Sympathomimetics (e.g. medicines to increase blood pressure or heart frequency or widen the windpipes such as epinephrine used in the treatment of severe allergic reactions and beta-2-agonists used in the treatment of asthma)

- * Medicines used for the treatment of erectile dysfunction (PDE-5 inhibitors e.g. sildenafil, tadalafil, vardenafil). 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. 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.

Terazosin Tablets with food, drink and alcohol

Taking food and drink has no influence on your treatment with Terazosin Tablets. Please be aware that alcohol may increase the risk of dizziness, light-headedness or drowsiness.

Pregnancy, breast-feeding and fertility

Terazosin Tablets are not recommended during pregnancy and breast-feeding. Ask your pharmacist or doctor for advice before taking any medicine

Driving and using machines

Terazosin tablets have a major influence on the ability to drive and use machines. Dizziness, light-headedness or drowsiness may occur with the initial dose or in association with missed doses and subsequent restart of terazosin therapy. Patients should be cautioned about these possible adverse events and the circumstances in which they may occur and advised to avoid driving or hazardous tasks for approximately the first 12 hours after the initial dose or when the dose is increased.

Terazosin Tablets contains lactose

This medicine contains milk sugar (lactose). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Terazosin Tablets

Always take Terazosin Tablets exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be taken once daily at bedtime, since there is always a risk of dizziness or weariness.

Avoid sudden changes in position or activities, which could cause dizziness or weariness. This is especially important if you are elderly (over 65 years of age) and/or when the treatment is started.

Treatment of high blood pressure (hypertension)

Your doctor will adjust your dose depending on how you respond to treatment. The usual dose schedule is shown below:

Treatment of hypertension	Recommended Dose of Terazosin Tablets
First week of treatment	1 mg daily
Second week of treatment	2 mg daily
Usual maintenance dose (if blood pressure is well controlled)	2 mg daily
If blood pressure is not controlled at a dose of 2 mg daily, the dose may be doubled at weekly intervals. Do not take more than the maximum dose indicated below.	
Maximum dose	20 mg daily

Your doctor will increase your dose of Terazosin until your blood pressure is well controlled.

Once your blood pressure is well controlled, your dose will not be changed. The usual maintenance dose is 2 mg per day, though sometimes it is necessary to use a higher dose. Do not take more than the maximum dose of 20 mg.

Treatment of high blood pressure with Terazosin is usually long-term. You should not stop therapy unless you are told to do so by your doctor. If it becomes necessary to interrupt your treatment with Terazosin for a short time, you should re-start treatment at the starting dose.

If your doctor prescribes another blood pressure medicine in addition to Terazosin, he/she will reduce the dose of Terazosin.

Treatment of benign prostatic hyperplasia (BPH)

Your doctor will adjust your dose depending on how you respond to treatment. The usual dose schedule is shown below:

Treatment of BPH	Recommended Dose of Terazosin Tablets
First week of treatment	1 mg daily
Second and third week of treatment	2 mg daily
Fourth week of treatment: response to treatment is reviewed and dose increased if necessary	up to 5 mg daily
Usual recommended dose	5 mg once daily
Maximum daily dose	10 mg daily

You may suffer short-lived undesirable effects (see Section 4 Possible side effects) each time your dose is increased. If any of these undesirable effects persists, your doctor may reduce your dose.

After 4 weeks on the maintenance dose, your doctor will assess how well you are responding to the treatment.

Children and adolescents

Terazosin is not recommended for children and adolescents under 18 years.

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PACKAGE LEAFLET: INFORMATION FOR THE USER (continued)

Elderly Patients

No dose adjustment is necessary in the elderly (over 65 years of age).

You should take your tablets at the same time each day e.g. bedtime. Swallow your tablets with half a glass of water. Do not break or crush them.

If you take more Terazosin Tablets than you should

If you have taken more Terazosin Tablets than you were told to, or if someone else has taken any Terazosin Tablets, contact accident and emergency department of your nearest hospital immediately for advice. Take any left over tablets or empty box with you for easier identification.

Taking too many tablets may cause your blood pressure to fall too low and other serious effects.

Likely symptoms of overdose

- The likely symptoms of overdose are:
- dizziness
 - confusion
 - fainting
 - shortness of breath
 - fall in blood pressure
 - palpitations (being able to feel your heart beating in your chest)
 - rapid heartbeat
 - nausea (feeling sick)
 - low levels of glucose (sugar) in the blood
 - low levels of potassium in the blood
 - muscle spasm (cramps)

If you forget to take Terazosin Tablets

If you forget to take a dose of Terazosin Tablets, you can take it as soon as you remember unless it is time for the next dose, in which case you should continue with your medication as prescribed. Do not take a double dose to make up for a forgotten dose. Do not take more than one tablet a day.

If you stop taking Terazosin Tablets

Do not stop taking Terazosin Tablets unless your doctor tells you to.

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

4 Possible side effects

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

The following side effects are important and will require immediate action if you experience them. You should stop taking Terazosin Tablets and see your doctor immediately if the following symptoms occur:

- Rare side effects may affect up to 1 in 1,000 people
- * Prolonged and painful penile erection

- Very rare side effects may affect up to 1 in 10,000 people
- * a sudden allergic reaction with shortness of breath, rash, wheezing and drop of blood pressure

The following side-effects have also been reported:

Common side effects (may affect up to 1 in 10 people):

- * Nervousness
- * Blurred or altered vision
- * Breathlessness (Dyspnoea)
- * Back pain
- * Palpitations
- * Nausea
- * Erectile failure
- * Dizziness
- * Itching
- * Sleepiness
- * Constipation
- * Skin rash
- * Tingling sensation in skin
- * Diarrhoea
- * Nasal congestion
- * Sensation of spinning around (Vertigo)
- * Vomiting
- * Sinusitis
- * Fast heart beat
- * Light-headedness
- * Nose bleed (Epistaxis)
- * Chest pain
- * Headache
- * Fluid retention and swelling
- * Feeling of weakness
- * Pain in the extremities
- * Fainting on standing

Uncommon side effects (may affect up to 1 in 100 people):

- * Depression
- * Decreased sex drive
- * Weight gain
- * Hives
- * Loss of consciousness

Rare side effects (may affect up to 1 in 1,000 people):

- * Urinary tract infection and urinary incontinence (primarily reported in post-menopausal women)

Very rare side effects (may affect up to 1 in 10,000 people):

- * Easy bruising or bleeding
- * Irregular heart beat (Atrial fibrillation)

In addition, the following side effects have been reported in clinical trials or during marketing experience (the side effects may not necessarily have been caused by terazosin): fever; pain in back, shoulder or abdomen; redness of skin; dry mouth; indigestion; flatulence; gout; pain in joints or muscles; anxiety; bronchitis; cold and flu symptoms; sore throat; cough; sweating; conjunctivitis; ringing in ears and frequent urination.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Terazosin Tablets

- * Keep out of the sight and reach of children.
- * Store in the original package in order to protect from light.
- * Do not use this medicine after expiry date, which is stated on the blister as well as carton. 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 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 substance is terazosin (as terazosin monohydrochloride dihydrate). Each tablet contains 5 mg of terazosin.

The other ingredients are lactose monohydrate, maize starch, talc and magnesium stearate (E470B). Terazosin 5 mg tablets also contain the colourant Iron oxide red (E172).

What Terazosin Tablets look like and contents of the pack

Terazosin Tablets 5 mg (Light pink coloured, round, flat tablets with bevelled edges and score line on one side of the tablet). The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Terazosin Tablets are available in PVC/PVdC - aluminium blister packs containing 28 tablets

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

Accord Healthcare Limited, Sage House, 319, Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Bulgaria	Теразозин Акорд 2 / 5 mg таблетки
Denmark	Terazosin Accord 2 / 5 mg tabletter
Ireland	Terazosin 2 / 5 mg Tablets
Malta	Terazosin 2 / 5 mg Tablets
Portugal	Terazosina Accord
Sweden	Terazosin Accord 2 / 5 mg Tablett
The Netherlands	Terazosine Accord 1 / 2 / 5 mg tabletten
United Kingdom	Terazosin 2 / 5 mg Tablets

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for help.