

PACKAGE LEAFLET: INFORMATION FOR THE USER

TERAZOSIN 2 mg TABLETS TERAZOSIN 5 mg TABLETS

Terazosin

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
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

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

Terazosin Tablets are used to:

- treat patients suffering from high blood pressure. They help reduce blood pressure.
- treat a condition called benign prostatic hyperplasia which is common in older men. This condition is caused by the prostate gland growing too big and obstructing, it can partially block the flow of urine from the bladder. This leads to some unpleasant symptoms such as:
 - a weak or interrupted urine flow
 - a need to pass water more frequently and/or a sudden need to pass water.

Terazosin can relax the muscle of the prostate gland and bladder exit to help relieve these symptoms.

Ask your doctor or pharmacist if you need additional information.

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

Do not take Terazosin Tablets:

- If you are allergic to active substance, or any of the other ingredients of this medicine (listed in section 6).
- 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Terazosin tablets if you experience or suffer from any of the following :

- 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 (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 be 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 tablets may cause complications during the surgery, which can be managed if your specialist is prepared in advance.

Other medicines and Terazosin Tablets

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

- Other medicines used in the treatment of high blood pressure (other antihypertensive agents including ACE inhibitors and water tablets)
- 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 and 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 and breast-feeding

Terazosin Tablets are not recommended during pregnancy and breast-feeding. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this 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 know that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Terazosin Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. It is important that you take the correct tablet at the correct time. The tablets should be swallowed with a drink of water. The first tablet of a new dose should be taken in the evening at bedtime. The following tablets of the same strength may be taken in the morning.

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.

After starting taking the tablets or changing the tablet strength, it is important that you DO NOT drive or undertake any hazardous tasks for 12 hours. This is especially important if you are elderly (over 65 years of age) and because dizziness, light-headedness or drowsiness can occur with the first dose, a change in dose or after missing doses and restarting treatment.

Use in Children and adolescents

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

If you take more Terazosin Tablets than you should

If you accidentally take an overdose (more than one tablet a day) call your doctor immediately. Taking too many tablets may cause your blood pressure to fall too low and other serious effects.

Symptoms of overdose may include :dizziness, confusion, fainting, shortness of breath, fall in blood pressure, pounding of your heart (palpitations , rapid heartbeatfeeling sick,muscle cramps, low levels of sugar in your blood,low levels of potassium in your blood.

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 tablet.

If you stop taking Terazosin Tablets

If you have not taken a tablet for several days you should NOT continue using the same tablets. Return to your doctor for advice.

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

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

The following serious side effects 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

- swelling of the face, hands, lips, tongue or throat and/or difficulty swallowing or breathing (anaphylactic reactions).

The following side-effects have also been reported:

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

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|--|-----------------------------|--------------------------------|
| • Nervousness | • Blurred or altered vision | • Breathlessness (Dyspnoea) |
| • Back pain | • Palpitations | • Nausea |
| • Impotence | • 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):

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|--------------|-----------------------|---------------|
| • Depression | • Decreased sex drive | • Weight gain |
|--------------|-----------------------|---------------|

- Hives (nettle rash)
- Transient 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 (thrombocytopenia)
- Irregular heart beat

In addition, the following side effects have been reported in either clinical trials or during marketing experience. However these may not necessarily have been caused by taking terazosin.

- facial swelling, fever, pain in the shoulder, neck or abdomen, redness of the skin, irregular heartbeat, indigestion, dry mouth, flatulence; gout; painful joints, arthritis, muscle pain, anxiety, difficulty sleeping, bronchitis, cold and flu symptoms, swollen or sore throat, cough, sweating, conjunctivitis, noises in the ear such as ringing or whistling (tinnitus) and frequent urination.

When taking Terazosin Tablets for the first time or when starting to take higher dose tablets, some people may experience dizziness, light-headedness or fainting. These effects may also occur when standing up quickly from a lying or sitting position. If this occurs you should lie down until you feel better then you should sit for a few minutes before standing again to prevent these effects returning. These side effects usually go away and should not return once you have become used to taking your tablets.

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

For Ireland - 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.

5. How to store Terazosin Tablets

- Keep this medicine 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 contains

The active substance is terazosin (as terazosin monohydrochloride dihydrate).

Each tablet contains 2 mg of terazosin.

Each tablet contains 5 mg of terazosin.

The other ingredients are lactose monohydrate, maize starch, talc and magnesium stearate (E470B).

Terazosin 2 mg tablets also contain the colourant Quinoline yellow (E104)

Terazosin 5 mg tablets also contain the colourant Iron oxide red (E172)

What Terazosin Tablets looks like and content of the pack

Terazosin Tablets 2 mg (Yellow coloured, round, flat tablets with beveled edges and score line on one side of the tablet)

This tablet can be divided in to equal halves

Terazosin Tablets 5 mg (Light pink coloured, round, flat tablets with beveled 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:

2mg tablets: 14, 28

5mg tablets: 28,98

Not all pack sizes may be marketed.

Marketing Authorisation Holder

United Kingdom

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

Ireland

Accord Healthcare Ireland Ltd,
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3526 KV Utrecht,

The Netherlands

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

Name of the Member State	Name of the medicinal product
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
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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