

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed with a doctor's prescription only

Terazosin Teva 5 mg Tablets

Composition: Each tablet contains: Terazosin (as hydrochloride dihydrate) 5 mg

For information about inactive ingredients and allergens, see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Terazosin Teva 5 mg is intended for symptomatic treatment of urinary obstruction caused by benign prostatic hyperplasia (BPH) and for treatment of mild to moderate hypertension.

Therapeutic group

Alpha-1-selective adrenoceptor blocking agents.

2. Before using this medicine

Do not use this medicine if:

- you are sensitive (allergic) to terazosin or to any of the other ingredients in this medicine. For a list of the inactive ingredients, see section 6 'Additional information' (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).
- you are sensitive to any of the following medicines: alfuzosin, indoramin, prazosin, tamsulosin, doxazosin
- you have ever fallen or fainted while urinating

Special warnings about using this medicine

Before taking the medicine tell your doctor if:

- you are taking other medicines for high blood pressure. If you started taking a medicine for high blood pressure whilst you are taking Terazosin Teva 5 mg, your doctor may need to adjust your dose of Terazosin Teva 5 mg
- you have any problems with your heart
- you are taking medicines for erectile dysfunction (e.g. tadalafil, sildenafil and vardenafil)
- you are planning to undergo cataract removal surgery

Terazosin Teva 5 mg must be used for treatment of benign prostatic hyperplasia (BPH) only after excluding other reasons for abnormal/interrupted urinary flow.

Terazosin Teva 5 mg 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 Teva 5 mg and then re-start. Do not start treatment in a new patient or re-start treatment after a break if you cannot reach a dosage of 1 mg and 2 mg.

Terazosin Teva 5 mg may also lead to decreases of certain laboratory values such as red blood cells or white blood cells.

If one of the conditions mentioned above applies to you or if you are not sure, tell your doctor before taking the medicine.

Children and adolescents

Terazosin Teva 5 mg is not recommended for children.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. In particular, inform your doctor or pharmacist if you are taking:

- other medicines to treat high blood pressure, including ACE inhibitors and diuretics
- medicines for erectile dysfunction (e.g. tadalafil, sildenafil, vardenafil, avanafil)

Some patients who take alpha blockers (from the class of drugs to which Terazosin belongs) 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 that 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 blockers, beta blockers calcium-channel blockers, clonidine, moxonidine, tizanidine, diazoxide, hyalalazine, 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
- medicines used for baldness (minoxidil)
- medicines for treating Parkinson's (e.g. levodopa and methylodopa)
- medicines for treating depression (monoamine oxidase inhibitors)

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

If you are going to have a general anaesthetic, you should tell the doctor or dentist in charge that you are taking Terazosin Teva 5 mg.

If you are undergoing eye surgery because of cataract (cloudiness of the lens), please inform your ophthalmologist before the operation that you are using or have previously used Terazosin Teva 5 mg. This is because Terazosin Teva 5 mg may cause complications during the surgery which can be managed if your eye specialist is prepared in advance.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Pregnancy

Terazosin Teva 5 mg should not be used during pregnancy unless you have been instructed to do so by your doctor. Decline in fertility and testicular atrophy were observed in rats in recurrent administration of dosages that are 20-30 times higher than the maximum dosage recommended for humans.

Driving and using machines

It is important to avoid driving, using machinery or carrying out hazardous tasks for 12 hours after taking your first tablet, as you may experience dizziness, light-headedness or drowsiness.

Important information about some of this medicine's ingredients

Each tablet of Terazosin Teva 5 mg contains approximately 115 mg lactose.

If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

Do not start treatment in a new patient if you cannot reach a dosage of 1 mg and 2 mg.

If you are unsure about when to take your tablets, you should consult your doctor for advice.

Do not exceed the recommended dose

Duration of treatment

You should continue to take your tablets unless your doctor tells you to stop. **Do not stop** just because you feel better.

Form of administration

You should take the tablet orally, at the same time each day at bedtime.

As no information is available, do not split, crush or chew the tablet.

If you have accidentally taken a higher dose, contact your doctor immediately.

If you have taken an overdose (more than one tablet in one day), or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you as well as all the remaining tablets.

Signs of overdose include low blood pressure, dizziness, lightheadedness, fainting, a rapid or irregular heartbeat and feeling sick.

If you forget to take the medicine at the scheduled time

If you forget to take a dose, take the next dose at the usual time. **DO NOT** take a double dose to make up for the missed dose. If you have not taken a tablet for several days, you may **NOT** continue using the same tablets, but should return to your doctor, who will give you a prescription for a starting dose of terazosin 1 mg. Do not re-start treatment if you cannot reach a dosage of 1 mg and 2 mg.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Terazosin Teva 5 mg may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them. Stop taking the medicine and seek medical advice immediately if you notice the following side effects (may be signs of an allergic reaction):

- Itching or skin rash
- Swelling of your face, lips or throat
- Difficulty in breathing or wheeziness

When taking Terazosin Teva 5 mg for the first time or when starting to take higher dose tablets, dizziness, light-headedness or fainting may occur. These effects may also appear when standing up quickly from a lying or sitting position. If you are affected by this, 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 the medicine.

Side effects of unknown frequency (frequency cannot be estimated from the existing information):

- low blood platelet count
- weakness, dizziness
- a fast or uneven heartbeat
- feeling sick
- swelling of the hands and feet
- weakness (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 which can cause dizziness or faintness on standing
- loss of consciousness
- vasodilation
- 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, flatulence
- dry mouth
- inflammation or pains in joints or muscles
- difficulty sleeping
- bronchitis (inflammation of the lungs)
- sinusitis (inflammation of the nasal passages)
- rhinitis (irritation and swelling of the mucous membrane inside the nose)
- nosebleeds
- flu-like symptoms, sore and irritated throat, cough
- skin rashes and itching
- sweating
- vision problems and conjunctivitis
- ringing in the ears
- increased frequency of urination, urinary tract infection, lack of bladder control
- low red blood cell count, laboratory tests abnormal

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

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health - by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor!
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- **Keep this medicine in a dry and dark place, below 25°C.**
- Medicines should not be disposed of via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Lactose monohydrate, starch, crospovidone, talc, povidone, magnesium stearate, iron oxide red and yellow.

What the medicine looks like and contents of the pack Brown-yellowish round tablet, "93" debossed on one side and "762" on the other.

The pack contains 30 tablets.

Manufacturer and license holder's name and address:

Teva Israel Ltd.,

124 Dvora HaNevi'a St., Tel Aviv 6944020

Registration number of the medicine in the Ministry of Health's National Drug Registry:

138.82.31457

This leaflet was revised in January 2022 according to MOH guidelines