PACKAGE LEAFLET: INFORMATION FOR THE USER

Terazostad 1 mg, 2 mg, 5 mg, 10 mg and 1 mg + 2 mg tablets

Terazosin

Read all of this leaflet carefully before you start taking this medicine.
- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Terazostad is and what it is used for

Terazostad belongs to a group of medicines called alpha blockers. It works by relaxing the blood vessels making it easier for the blood to flow through. It can also relax the muscle of the bladder and bladder exit.

Terazostad is used to:
- treat mild to moderate high blood pressure (hypertension).
- treat urinary problems due to 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. Before you take Terazostad

DO NOT take Terazostad
- If you are allergic (hypersensitive) to terazosin, or to a structurally similar alpha-adrenergic antagonist, the colourant “sunset yellow” FCF (E 110) or to any of the other ingredients of the Terazostad tablets (see section 6 “Further information” at the end of the leaflet)

- If you suffer or have ever suffered from micturition syncope. This is a brief loss of consciousness that occurs when passing water, or just after passing water. It is more common if you have to get up at night to urinate.

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

- **orthostatic hypotension** (low blood pressure which occurs on standing up). This can cause fainting, unsteadiness or vertigo (a sensation of spinning around). 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 suffer fainting and orthostatic hypotension if:
  - your dose of Terazostad 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 Terazostad.

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

Taking other medicines
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
- 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)
- Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headness, 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.

Taking Terazostad with food and drink
Terazosin tablets should be swallowed whole and not be chewed. Terazostad can be taken with or without food. Please be aware that alcohol may increase the risk of dizziness, light-headedness or drowsiness.

Pregnancy and breast-feeding
Always ask your doctor or pharmacist for advice before taking any medicine.

There are no adequate data from the use of Terazostad in pregnant women. Therefore, if you are pregnant, you must not take Terazostad without consulting your doctor first. At any case, you should not take this medicine shortly before birth.

It is not known if Terazostad passes over into the breast milk. Therefore, you must not take Terazostad if you are breast-feeding without consulting your doctor first.

Driving and using machines
You should not drive or use machines for 12 hours after having started

treatment with Terazostad or after having changed the dose. This medicine can cause dizziness, light-headedness or drowsiness. The risk of these side effects is higher when your dose is increased or if you drink alcohol.

Important information about some of the ingredients of Terazostad tablets
Milk sugar (lactose)
Terazostad tablets contain milk sugar (lactose). If you have been told that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

Colourants
Terazostad 2 mg tablets contain the colourant Sunset Yellow FCF (E110). This can cause allergic-type reactions including asthma. Such allergy is more common if you are allergic to aspirin.

3. How to take Terazostad

Always take Terazostad exactly as your doctor has told 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.

Terazostad tablets should be swallowed whole and not be chewed.

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 Terazostad 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 Terazostad 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 Terazostad 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 Terazostad for a short time, you should re-start treatment at the starting dose.

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

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

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

If you take more Terazostad than you should
If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department immediately for advice.

Taking too may 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 Terazostad
If you forget to take a dose of Terazostad, just take the next dose at the usual time. Do not try to make up for the missed dose and do not take two doses at once.

If you stop using Terazostad
Do not stop or change your treatment without talking to your doctor.

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

4. Possible side effects

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

As with other alpha-blockers, Terazostad can cause fainting. Fainting may occur within 30-90 minutes of the first dose. Occasionally a rapid heart rate develops just before the fainting occurs. Starting treatment with a 1 mg dose at bedtime helps to avoid low blood pressure and fainting.

The evaluation of the side effects is based on the following frequencies:

Very common	in more than 1 in 10 patients treated
Common	in less than 1 in 10, but more than 1 in 100 patients treated
Uncommon	in less than 1 in 100, but more than 1 in 1000 patients treated
Rare	in less than 1 in 1000, but more than 1 in 10 000 patients treated
Very rare	in less than 1 in 10 000 patients treated
Not known	frequency cannot be estimated from the available data

Common:
- nervousness
- sleepiness (somnolence)
- pins and needles (paraesthesia)
- blurred vision
- abnormal colour vision
- palpitations (being able to feel your heart beating in your chest)
- rapid heartbeat
- chest pain
- shortness of breath
- nasal congestion (a blocked nose)
- sinusitis (inflammation of the lining of the sinuses. The sinuses are cavities full of air, located in the bones around the nose)
- nose bleed
- nausea (feeling sick)
- constipation
- diarrhoea
- vomiting
- itching
- rash
- back pain
- impotence
- dizziness
- light-headedness
- fainting (especially when standing up quickly from a lying or sitting position - postural hypotension)
- weakness
- swelling due to an accumulation of fluid under the skin (oedema)
- headache
- pain in the limbs

Uncommon:
- depression
- hives (urticaria)
- decreased libido
- weight gain
- fainting

Rare:
- infection of the urinary tract and urinary incontinence (mostly common in postmenopausal women)
- long-lasting, involuntary erection of the penis (priapism)

Very rare:

- anaphylactic reactions. These are serious, sometimes fatal allergic (hypersensitivity) reactions.
- thrombocytopenia (low number of blood platelets, which may increase the risk of bruises and bleedings)
- irregular heart beat (atrial fibrillation)

The values of certain blood tests may be lower than normal during treatment with Terazostad e.g.:
- values of the red cells in the blood (haematocrit, haemoglobin)
- number of white blood cells
- the level of protein in the blood

The following side effects also occurred during treatment with Terazostad, but cannot be clearly associated with it:
- swelling of the face; fever; pain in the abdomen, neck and shoulder; widening of the blood vessels (vasodilation); irregular heart beat; dry mouth; upset stomach; flatulence (wind); gout; joint pain (arthralgia); inflammation of joints (arthritis); joint disorders; muscle pain (myalgia); anxiety; sleeplessness (insomnia); bronchitis; flu symptoms; pharyngitis (an inflammation of the throat); runny nose (rhinitis); cold symptoms; increased cough; sweating; abnormal vision; inflammation of the eyes (conjunctivitis); ringing or other noises in the ears (tinnitus); increase in the number of times urine is passed (urinary frequency).

only for Terazostad 2 mg:
The colourant sunset yellow (E 110) may cause allergic reactions (see also section 2, Important information about some of the ingredients of Terazostad tablets).

If any of the side effects gets serious, or if you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Terazostad

Keep out of the reach and sight of children.

Do not use Terazostad after the expiry date, which is stated on the carton and blister pack after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of in wastewater or in the household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

6. Further information

What Terazostad contains
The active substance is terazosin (as terazosin hydrochloride dihydrate).

Terazostad 1 mg tablets
1 tablet contains 1 mg of terazosin.

Terazostad 2 mg tablets
1 tablet contains 2 mg of terazosin.

Terazostad 5 mg tablets
1 tablet contains 5 mg of terazosin.

Terazostad 10 mg tablets
1 tablet contains 10 mg of terazosin.

The other ingredients are:
- lactose monohydrate
- powdered cellulose
- croscarmellose sodium
- magnesium stearate

Terazostad 2 mg tablets also contain the colourant sunset yellow FCF (E110).

Terazostad 5 mg tablets also contain the colourant iron oxide red (E172).

Terazostad 10 mg tablets also contain the colourant indigotine lake (E132).

What Terazostad looks like and contents of the pack
Terazostad 1 mg tablets are white, round tablets.
Terazostad 2 mg tablets are orange, round tablets, with a break mark on one side.
Terazostad 5 mg tablets are red, round tablets.
Terazostad 10 mg tablets are blue, round tablets.

Terazostad is available in PVC/aluminium blister packs containing:

Packs containing one strength of tablet:
1 mg tablets: 10, 28.
2 mg tablets: 10, 14, 20, 28, 30, 50, 84, 98, 100.
5 mg tablets: 14, 20, 28, 30, 50, 84, 98, 100.
10 mg tablets: 28, 30, 84, 98, 100.

Packs containing two strengths of tablet:
1 mg x 7 + 2 mg x 7
1 mg x 7 + 2 mg x 14
1 mg x 7 + 2 mg x 21
1 mg x 3 + 2 mg x 11

Not all pack sizes may be marketed.

Marketing authorisation holder:

[to be completed nationally]

In Sweden:
Stada Arzneimittel AG
Stadastrasse 2-18
DE-61118 Bad Vilbel
Germany

Manufacturer:
[to be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:
Germany: Terazosin AL 2/5 mg Tabletten
Sweden: Terazostad tablett 1/2/5/10/1 mg + 2 mg

This leaflet was last approved in 14 January 2010