

Package Leaflet: Information for the user

Tizanidine 4mg tablets

(tizanidine hydrochloride)

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.

The name of your medicine is Tizanidine 4mg tablets but will be referred to as Tizanidine throughout this leaflet. Please note that this leaflet also contains information about other strength Tizanidine 2mg tablets.

What is in this leaflet

1. What Tizanidine is and what it is used for
2. What you need to know before you take Tizanidine
3. How to take Tizanidine
4. Possible side effects
5. How to store Tizanidine
6. Contents of the pack and other information

1 What Tizanidine is and what it is used for

Tizanidine belongs to a group of drugs called skeletal muscle relaxants.

Tizanidine is used to relieve the stiffness and restriction of muscles resulting from multiple sclerosis, injury or diseases of the spinal cord.

2 What you need to know before you take Tizanidine

Do not take Tizanidine:

- if you are allergic to tizanidine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have severe liver problems
- if you are taking medicines such as **fluvoxamine** (for depression) or **ciprofloxacin** (an antibiotic) (see 'Other medicines and Tizanidine')
- if you have rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

Warnings and precautions

Talk to your doctor before you start to take this medicine if you:

- have kidney problems
- have liver problems.

Other medicines and Tizanidine

Talk to your doctor if you are taking any of the following:

- any medicine that may affect the heart's normal rhythm
- any medicine to treat an abnormal heart rhythm, such as amiodarone, mexiletine or propafenone
- cimetidine (for indigestion and digestive ulcers)
- some antibiotics known as fluoroquinolones, such as enoxacin, pefloxacin or norfloxacin
- rofecoxib (a painkiller)
- ticlopidine (to prevent blood clots)
- any medicine to treat high blood pressure including diuretics (water tablets)
- beta blockers e.g. atenolol, propranolol (used to lower blood pressure and slow the heart rate)

- digoxin (used to treat congestive heart failure and problems with heart rhythm)
- sleeping tablets, e.g. temazepam
- the contraceptive pill
- any other medicines which, when taken with Tizanidine, might affect your heart's rhythm: check with your doctor or pharmacist.

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

Tizanidine contains lactose

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

Tizanidine with food and drink

- **DO NOT** drink alcohol while taking Tizanidine, as it may make the sedative effect of Tizanidine worse.

Pregnancy and breast-feeding

- if you are pregnant or planning to become pregnant ask your doctor for advice before taking this medicine
- it is not recommended to take Tizanidine tablets while breast-feeding.

Driving and using machines

- Tizanidine may cause drowsiness, dizziness and decreased blood pressure. If you are affected, **DO NOT** drive or operate machinery.

3 How to take Tizanidine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed preferably with a drink of water. The recommended dose is:

- **Adults:**
Your doctor will usually start your treatment with a dose of one 2mg tablet taken once a day.
Your doctor will gradually increase the number of tablets you take, and spread them out over the day into three or four doses. The exact dose will be set by your doctor according to your response to treatment.
Your total dose should not be more than 36mg a day.
- **Elderly:**
Your doctor will decide if you should take Tizanidine.
- **Children (under 18 years):**
Tizanidine is not recommended for use in children.
- **Patients with kidney problems:**
Treatment should be started with 2mg once daily. Your doctor will advise you on how to increase your dose.

If you take more Tizanidine than you should

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 casualty department or your doctor immediately.

An overdose is likely to cause dizziness, low blood pressure, feeling sick, being sick, pin-point pupils, breathing problems, coma, restlessness, and sleepiness.

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 Tizanidine

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tizanidine

DO NOT stop taking your medicine without talking to your doctor first even if you feel better. Treatment with Tizanidine tablets should be stopped gradually, especially if you have been taking a high dose or with other blood pressure lowering medicine. Stopping treatment suddenly may cause an increase in heart rate and high blood pressure.

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

4 Possible side effect

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

Stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- 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 side effect. You may need urgent medical attention or hospitalisation.

Other side effects include:

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

- drowsiness, tiredness, dizziness
- reduction in blood pressure, decrease in heart rate
- dry mouth.

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

- hallucinations (hearing or seeing things that are not real)
- difficulty in sleeping
- feeling sick, stomach upsets
- changes in the function of the liver - it may be necessary to have blood tests to monitor this
- muscle weakness.

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

- yellowing of the eyes or skin and/or production of dark urine, which may be caused by inflammation of the liver. Tell your doctor immediately if you experience this side effect
- liver failure.

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

- confusional state
- stomach pain
- vomiting
- itching
- blurred speech
- allergic reactions.

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 at: 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 Tizanidine

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not transfer to another container.

Do not take the tablets after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.

If the tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

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

6 Contents of the pack and other information

What Tizanidine contains

The active ingredient in the Tizanidine is tizanidine hydrochloride.

Each tablet contains 4mg tizanidine (as hydrochloride).

The other ingredients are lactose, microcrystalline cellulose, stearic acid and colloidal anhydrous silica.

What Tizanidine looks like and contents of the pack

Tizanidine is white to off-white, biconvex, round tablets debossed 'T4' on one side and divided into quarters by score lines on the reverse.

It is available in pack sizes of 100 and 120 tablets.

Manufactured by: TEVA Pharmaceutical Works Private Limited Company, Pallagi ut 13, 4042 Debrecen, Hungary.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Tizanidine 4mg tablets; PL 18799/4069

Leaflet date: 25.01.2024

POM

Blind or partially sighted?

Is this leaflet hard to see or read?

Call **0208 515 3763** to obtain the leaflet in a format suitable for you.

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