

## Tizanidine 2 mg or 4 mg Tablets

### 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 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 2 mg 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 36 mg 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 2 mg 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](http://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 this medicine out of the sight and reach of children.**

Do not store above 30°C. Do not transfer to another container.

Do not use this medicine after the expiry date that is stated on the 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 you no longer use. These measures will help protect the environment.

### **6 Contents of the pack and other information**

**What Tizanidine tablets contain:**

- The active substance is tizanidine hydrochloride
- The other ingredients are lactose, cellulose microcrystalline, stearic acid and silica colloidal anhydrous.

**What Tizanidine tablets look like and contents of the pack:**

- Tizanidine tablets are white to off-white, biconvex, round tablets
- The 2 mg tablets are debossed 'T2' on one side and have a scoreline on the reverse
- The 4 mg tablets are debossed 'T4' on one side and divided into quarters by scorelines on the reverse
- The 2 mg tablets are available in pack sizes of 15, 20, 30, 50, 100, 120 and 500
- The 4 mg tablets are available in pack sizes of 20, 30, 50, 100, 120, 200 and 500. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

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**Manufacturer**

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**This leaflet was last revised: 10/2021**

PL 00289/0648-0649



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EAS4220c