

# Tizanidine 2 mg and 4 mg Tablets

Tizanidine

**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. 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 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 medicines called skeletal muscle relaxants.
- Your medicine 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 or to any of the ingredients of this medicine (listed in section 6).
- if you have severely impaired liver function.
- if you are taking medicines such as fluvoxamine (for depression) or ciprofloxacin (an antibiotic) (see also 'Other medicines and Tizanidine' below)

### Warnings and Precautions

Talk to your doctor or pharmacist before taking Tizanidine:

- if you have kidney problems. In this situation your doctor may adjust your dose.
- if you have heart problems such as coronary artery disease. Regular clinical laboratory and ECG monitoring is recommended during treatment with tizanidine.
- if you have liver problems. Liver function tests should be monitored monthly for the first four months of treatment in all patients and in those who develop symptoms suggestive of liver dysfunction or where jaundice occurs.
- if you have low blood pressure.

### Children and adolescents

Tizanidine is not recommended for use in children and adolescents.

### Other medicines and Tizanidine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is especially important if you are taking any of the following;

- 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).
- The contraceptive pill. You may respond to a lower dose of Tizanidine if you are taking the pill.
- Ticlopidine (to prevent blood clots).
- Any medicine to treat high blood pressure, including diuretics (water tablets).
- Beta blockers, e.g. atenolol, propranolol.
- Digoxin (used to treat congestive heart failure and problems with heart rhythm).
- Any sedatives (sleeping pills or medicines for anxiety), e.g. temazepam.
- Any other medicines which, when taken with Tizanidine, might affect your heart's rhythm: check with your doctor or pharmacist.

Tizanidine must not be taken at the same time as fluvoxamine (to treat depression) or ciprofloxacin (an antibiotic) (see 'Do not take Tizanidine if you', above). Clinically significant and

prolonged hypotension may result along with somnolence, dizziness and decreased psychomotor performance.

### Tizanidine with food, drink and alcohol

Tizanidine can be taken independently of meals. Alcohol may increase the sedative effect of Tizanidine. It is recommended not to drink alcohol while taking Tizanidine.

### Pregnancy and breast-feeding

It is not recommended to take Tizanidine during pregnancy or while you are 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

Tizanidine may cause drowsiness or dizziness (see section 4). Alcohol and sedatives may increase this effect. If you are affected do not drive or operate machinery.

### Tizanidine contains lactose

Tizanidine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## 3.How to Take Tizanidine

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

The recommended dosage instructions are given below:

### Adults:

Your doctor will usually start you on a single dose of 2 mg which will then be gradually increased. Your dose should not be increased more often than every three to four days. As the dose is increased your doctor will advise you to spread the dose out to three or four times a day.

The recommended daily dose is between 12 and 24 mg. The maximum daily dose is 36 mg.

### Elderly:

Your doctor will decide if you should take Tizanidine.

### Patients with kidney problems:

Treatment should be started with 2 mg once daily. Your doctor will advise you on how to increase your dose.

### Method of administration:

Tizanidine is for oral use. The tablets should be swallowed with a glass of water.

### 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.

Overdose may cause nausea, vomiting, low blood pressure, a slow or abnormal heart beat, dizziness, small pupils, difficulty breathing, coma, restlessness or sleepiness.

### If you forget to take Tizanidine

If you forget to take one or more of your tablets, be sure to take only your usual number of tablets at the time of your next dose. Do not take a double dose to make up for a forgotten dose.

### If you stop taking Tizanidine

Do not stop taking Tizanidine unless your doctor tells you to. Treatment with Tizanidine should be stopped gradually, especially if you have been taking a high dose, unless your doctor has told you otherwise. Stopping treatment suddenly may cause effects such as an increase in heart rate and high blood pressure. Rebound increase in blood pressure might lead to stroke (cerebrovascular accident).

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.

### Serious side effects

You should tell your doctor **immediately** if you experience signs of any of the following:

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

- Allergic reaction (itching or rash).

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

- Inflammation of the liver (hepatitis) or liver failure, which may lead to yellowing of the eyes or skin and/or production of dark urine.

**Not Known (cannot be estimated from the available data):**

- Allergic reactions (swelling of the face, lips, tongue or throat, sudden wheezing, difficulty swallowing or breathing).

### Other side effects

The following side effects have also been reported:

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

- Drowsiness, tiredness, dizziness
- Reduction in blood pressure
- Increase of blood pressure when stopping the treatment suddenly
- Dry mouth
- Decrease or increase in heart rate.

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

- Hallucinations
- Sleep disorders including difficulty in sleeping
- Changes in the function of the liver - it may be necessary to have blood tests to monitor this
- Muscle weakness
- Nausea, stomach upsets.

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

- Abnormal heart rhythms
- Headache, abnormal movements
- Difficulty focusing the eyes
- Loss of appetite
- Anxiety
- Stomach pain
- Vomiting
- Itching
- Blurred speech

### 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

#### Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

#### United Kingdom

You can report side effects directly using the Yellow Card scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

## 5.How to store Tizanidine

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date shown on the carton and blister foil after the abbreviation 'EXP'. 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 any medicines you no longer use. These measures will help protect the environment.

## 6.Contents of the pack and other information

### What Tizanidine contains:

- The active ingredient is tizanidine. Each tablet contains 2 mg or 4 mg of tizanidine (as hydrochloride).
- The other ingredients are lactose anhydrous, cellulose microcrystalline, stearic acid and silica colloidal anhydrous.

### What Tizanidine looks like and the contents of the pack:

- Tizanidine is supplied in white, round tablets.
- Tizanidine 2 mg is marked 'N 62' on one side.
- Tizanidine 4 mg is grooved on one side and marked 'N 63' on the other side.
- The 2 mg tablets are available in pack sizes of 28, 30, 34, 84, 90, 91, 98, 100, 105 and 120 tablets.
- The 4 mg tablets are available in pack sizes of 10, 28, 30, 34, 84, 90, 91, 98, 100, 105 and 120 tablets.
- Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### Marketing Authorisation Holder

Niche Generics Limited,  
1 The Cam Centre, Wilbury Way, Hitchin, Hertfordshire, SG4 0TW, United Kingdom.

#### Manufacturer

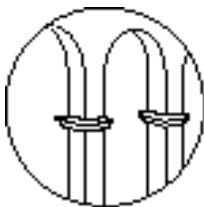
Niche Generics Limited,  
Unit 5, 151 Baldoyle Industrial Estate, Dublin 13, Ireland

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

Ireland: Tizanidine 2 mg and 4 mg tablets

United Kingdom: Tizanidine 2 mg and 4 mg tablets

**This leaflet was last revised in May 2016.**



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Title:	Tizanidine 2mg/4mg for Niche UK/IE
MA Number/s:	IE: PA 1063/035/001, 1063/035/002 UK: PL 19611/0158, 19611/0159
Date of Origination:	19/03/2009
Dimensions:	480mm x 145mm
Colours:	Black ■
Item Code:	N/A
Pharmacode:	TBD
Version Number:	9
Revision Date:	24/05/2016
Reason for Revision:	22/12/15 - Incorporation of new safety information from PSUSA procedure and to align text with current QRD template 24/02/2016 - amendments are requested during procedure 24/05/2016 - amendments to section 4 during assessment