PACKAGE LEAFLET

Package leaflet: Information for the patient

Tizanidine 2 mg Tablets
Tizanidine 4 mg Tablets

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, pharmacist or nurse.
- 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, pharmacist or nurse. 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

Your tablets contain the active substance tizanidine, which belongs to a group of medicines called muscle relaxants. Tizanidine acts on your central nervous system and can help to relieve painful muscle spasms and cramping and tightness of muscle due to multiple sclerosis or other disease or injury affecting the spinal cord.

2. What you need to know before you take Tizanidine

Do not take Tizanidine:
- if you are allergic to tizanidine 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')

Tizanidine is not suitable for children or the elderly.

Warnings and precautions

Talk to your doctor or pharmacist before taking Tizanidine:
- if you have kidney problems.
- if you have liver problems.

Your doctor will decide if you need blood tests to check that your liver is working properly.

Other medicines and Tizanidine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Tizanidine if you are already taking any of the following:
- fluvoxamine (for depression)
- ciprofloxacin (an antibiotic)

Tell your doctor or pharmacist if you are taking any of the following medicines as they may affect the way Tizanidine works or makes side effects more likely:
- the oral contraceptive pill
- antibiotics called norfloxacin, enoxacin, pefloxacin or rifampicin
- ticlopidine (to prevent blood clots)
- cimetidine (for indigestion and stomach ulcers)
- any medicine with a sedative effect such as sleeping pills, medicines for anxiety (e.g. diazepam or temazepam), other muscle relaxants (e.g. baclofen) or antihistamines (e.g. chlorphenamine)
- medicines for high blood pressure, including diuretics (water tablets), beta-blockers (e.g. atenolol, propranolol) or clonidine
- medicine to treat abnormal heart rhythms (e.g. digoxin, amiodarone, mexiletine or propafenone)
- any other medicine that could affect the rhythm of your heart (QT prolongation, e.g. amitriptyline and azithromycin) - check with your doctor or pharmacist

Taking Tizanidine if you are a smoker
You should also tell your doctor if you are a smoker as your doctor may need to change your dose.

Tizanidine with alcohol
You should not drink alcohol with Tizanidine. Alcohol may increase the chance of you feeling drowsy or experiencing side effects while taking Tizanidine. Consult your doctor before taking Tizanidine with alcohol.

Pregnancy and breast-feeding
Tizanidine should not be used during pregnancy or 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
Do not drive or operate machinery if you have blurred vision, feel drowsy or dizzy whilst taking Tizanidine.

Tizanidine tablets contain lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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.

Swallow the tablets with a drink of water. You may take the tablets with or without food.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Use in adults: The recommended dose is 2 mg Tizanidine (one 2 mg tablet) taken once a day.

If needed, every 3 or 4 days, your doctor may increase the dose by 2 mg of Tizanidine. You should take larger doses of Tizanidine as 3 or 4 divided doses during the day. The exact dose will depend on your response to the tablets. The maximum daily dose is 36 mg of Tizanidine.

Use in children and adolescents: Tizanidine **should not** be given to children or adolescents under 18 years old.

Elderly: If you are elderly you should not take Tizanidine unless your doctor tells you otherwise.

Kidney problems: In patients with kidney disease the dose may be increased more slowly and you may need blood tests to check on your kidneys.

If you take more Tizanidine than you should
If you accidentally take too many tablets, contact your doctor or go to the nearest hospital emergency department immediately. Take the packet and this leaflet with you so that the doctor will know what you have taken. Signs of overdose may include feeling sick (nausea), being sick (vomiting), low blood pressure, dizziness, a decrease in the size of the pupils of the eye, breathing problems, coma, restlessness, abnormal heartbeat or sleepiness.

If you forget to take Tizanidine
Unless it is nearly time for your next dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tizanidine
Do not stop or change your treatment before talking to your doctor. Your doctor will gradually reduce your dose and regularly check your blood pressure to prevent signs of withdrawal.

The following side effects have been observed if you stop taking tizanidine suddenly, especially if you have been taking tizanidine for a long time, been taking a high dose or if you are taking medicines to lower your blood pressure:
- high blood pressure
- increased heart rate, which may result in blurred vision or headache

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

4. Possible side effects

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

You should tell your doctor immediately or go to the nearest hospital emergency department if you experience signs of any of the following:

Very rare (may affect up to 1 in 10,000 people)
- liver damage, such as yellowing of the eyes or skin, abdominal pain, tiredness, fever, pale stools and/or dark urine

Not known (cannot be estimated from the available data)
- an allergic reaction, such as swelling of the face, lips, tongue or throat, sudden wheezing, difficulty swallowing or breathing itching or nettle rash (hives)
- convulsions (fits)

Other side effects include:

Very common (may affect more than 1 in 10 people)
- drowsiness, feeling tired
- weak muscles
- dry mouth, problems with your gut
- dizziness

Common (may affect up to 1 in 10 people)
- difficulty falling asleep or other sleeping problems
- a drop in blood pressure causing you to feel lightheaded or feel dizzy
- feeling sick (nausea)
- increase in levels of liver enzymes in the blood (this may be seen with a blood test)
- slow heart beat

Rare (may affect up to 1 in 1,000 people)
- seeing, hearing or feeling things that are not real (hallucinations). More likely if you are taking other drugs which may themselves cause hallucinations e.g. antidepressants

Not known (cannot be estimated from the available data)
- confusion
- vertigo (a feeling of dizziness or spinning)
- loss of consciousness
- feeling of unusual weakness
- blurred vision
- signs of withdrawal (see section 3,"If you stop taking Tizanidine")
- stomach pain, vomiting
- itching
- blurred speech

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any 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.
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 25 °C.

Do not use this medicine after the expiry date which is stated on the carton after "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 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 substance is tizanidine. Each 2 mg tablet contains 2 mg tizanidine (as hydrochloride). Each 4 mg tablet contains 4 mg tizanidine (as hydrochloride).

The other ingredients are: colloidal anhydrous silica, stearic acid, microcrystalline cellulose and anhydrous lactose (see section 2 “Tizanidine contains lactose”).

What Tizanidine looks like and contents of the pack

Tizanidine 2 mg Tablets are white, and marked “TI” and “2” on either side of a score line on one side and “G” on the other.

Tizanidine 4 mg Tablets are white and marked “TI” and “4” on one side and a cross-shaped score line on the other side.

Tizanidine tablets are available in blister strips of plastic/aluminium foil in a carton or in plastic containers with plastic caps in packs of 15, 30, 50 and 120.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Viatris,
Station Close,
Potters Bar,
EN6 1TL,
United Kingdom.

Manufacturer
Gerard Laboratories Ltd,
35-36 Baldoyle Industrial Estate,
Grange Road,
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Generics [UK] Limited
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