

Package leaflet: Information for the patient

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

1. What Tizagelan is and what it is used for

Tizagelan belongs to a group of medicines called skeletal muscle relaxants.

Tizanidine] can be prescribed by your doctor for muscle cramps caused by certain conditions of the spine or as a result of surgery on the musculoskeletal system (for example vertebrae or hip joint). Tizagelan can also be prescribed for muscle cramps as a result of disorders of the nervous system, such as multiple sclerosis and after a stroke.

2. What you need to know before you take Tizagelan

Do not take Tizagelan,

- if you are allergic to tizanidine or any of the other ingredients of this medicine (listed in section 6).
- if your liver function is severely impaired.
- if you are taking certain medicines such as fluvoxamine (to treat depressions) or ciprofloxacin (an antibiotic) (see also 'Other medicines and Tizagelan').

Warnings and precautions

Talk to your doctor before taking Tizagelan,

- if you have a severe kidney disease. You may require a lower dose.
- if you have heart problems such as coronary artery disease.
- if you have liver problems. Maybe your doctor will check your liver enzymes regularly, especially when you take high doses. Stop taking Tizagelan if your skin or whites of the eyes turns yellow ('jaundice'), or if you develop unexplained nausea, anorexia or tiredness, and inform your doctor immediately.
- if you have kidney problems.

Children and adolescents

Tizagelan is not recommended for children and adolescents under 18 years of age because experience with tizanidine in this patient group is limited.

Other medicines and Tizagelan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tizagelan must not be taken at the same time as fluvoxamine (to treat depressions) or ciprofloxacin (an antibiotic) (see 'Do not take Tizagelan').

Please tell your doctor or pharmacist especially if you are taking

- any medicine to treat an abnormal heart rhythm, such as amiodarone, mexiletine, propafenone, or verapamil.
- cimetidine or famotidine (for indigestion and digestive ulcers).
- some antibiotics, such as rifampicin, or so-called 'fluoroquinolones' (such as enoxacin, pefloxacin, norfloxacin).
- rofecoxib, a pain-killer.
- acyclovir, an antiviral medicine.
- the contraceptive pill. You may respond to a lower dose of Tizagelan 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).
- any other medicines which, when taken with tizanidine, might affect your heart rhythm. Check with your doctor or pharmacist.

Tizagelan with food and alcohol

Tizagelan can be taken with or without food.

Do not take Tizagelan with alcohol as it may enhance the sedative effect of tizanidine.

Tizagelan and smoking

Smoking may decrease the effect of tizanidine.

Pregnancy and 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.

It is not recommended to take Tizagelan if you are pregnant or if you are breast-feeding, as the effects of Tizagelan on pregnancy, on the unborn baby, or on your infant are not known. Your doctor will decide if you should take Tizagelan.

Driving and using machines

Tizagelan may cause drowsiness and dizziness. This may affect your ability to drive or operate any tools or machinery. You should not drive or use machines until you know whether this medicine affects your ability to perform these activities.

Tizagelan contains sucrose and 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 Tizagelan

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

For skeletal muscle cramps as a result of surgery and spinal disorders

The recommended dose for adults is 2-4 mg 3 times daily.

In severe cases, an additional dose of 2-4 mg may be required. This last dose should be taken late at

night.

For muscle cramps due to disorders of the nervous system

The usual starting dose for adults is 2 mg 3 times daily.

After this, the dosage can be increased gradually to 12-24 mg, divided into 3-4 equal amounts daily.
The maximum daily dose is 36 mg.

Use in children and adolescents up to the age of 18 years

Tizagelan should not be taken by children, because the use by children is examined insufficiently.

Elderly (65 years and older)

Experience with the use of Tizagelan in the elderly is limited. Additionally, kidney function may be impaired in the elderly. Therefore, Tizagelan should be used with caution in this patient group.

How to take Tizagelan

Tizagelan is for oral use.

The tablets should be swallowed with a glass of water.

You may take Tizagelan with or without food.

If you have the impression that Tizagelan is too strong or too weak, talk to your doctor or pharmacist.
The tablet can be divided into equal doses.

If you take more Tizagelan than you should

If you (or someone else) take too many tablets 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 Tizagelan

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 Tizagelan

Do not stop taking Tizagelan unless your doctor tells you to. Treatment with Tizagelan 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.

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.

With low doses, such as those recommended for the relief of painful muscle spasms, side effects are usually mild and transient.

With the higher doses recommended for the treatment of spasticity, the side effects appear more frequently and more pronounced, but seldom severe enough that you have to discontinue the treatment.

The following side effects have been reported:

Very common (may affect more than 1 in 10 people)

- Difficulty sleeping or falling asleep
- Dry mouth, gastrointestinal disturbances
- Muscular weakness

Common (may affect up to 1 in 10 people)

- Sleepiness, drowsiness, dizziness, fatigue
- Slow or fast heartbeat
- Low or decreased blood pressure
- Nausea

Uncommon (may affect up to 1 in 100 people)

- Increased blood level of liver enzymes

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

- Infections, stuffy or runny nose, infection in the throat
- Allergic reactions:
 - o Hives
 - o Serious, life-threatening allergic reaction requiring immediate medical treatment. The reaction may include extremely low blood pressure, swelling of the throat, difficulty breathing, and loss of consciousness.
- Confusion, nervousness, hallucinations (seeing and/or hearing things that are not real)
- Headache
- Difficulty in controlling movements, involuntary muscle movements, difficulty in speaking
- Fainting
- A feeling of 'spinning' (vertigo)
- Difficulty focusing the eyes, blurred vision
- Abnormal heart rhythms
- Vomiting, abdominal pain, constipation
- Infection or failure of the liver
- Itching, rash, infection of the skin
- Infection of the urinary tract
- Abnormally frequent passage of relatively small quantities of urine
- Loss of appetite
- Feeling of weakness, discontinuation syndrome, flu-like illness

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 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 Tizagelan

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

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

No special storage conditions.

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 Tizagelan contains

- The active substance is tizanidine. Each tablet contains 2 mg tizanidine (as 2.29 mg tizanidine hydrochloride). / 4 mg tizanidine (as 4.57 mg tizanidine hydrochloride).
- The other ingredients are lactose monohydrate, pregelatinised starch (maize), macrogol 4000, stearic acid, sucrose, magnesium stearate.

What Tizagelan looks like and contents of the pack

Tizagelan 2 mg tablets are white to yellowish coloured, round and biconvex tablets, with a break score on one side and with a diameter of about 8 mm.

Tizagelan 4 mg tablets are white to yellowish coloured, round and biconvex tablets, with a cross break score on one side and with a diameter of about 8 mm.

Tizagelan is available in PVC/PVdC/PVC-aluminium blister packs with 10, 30, 60, 90, 100 or 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

G.L. Pharma GmbH
Schlossplatz 1, 8502 Lannach, Austria

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

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| - Austria | Tizagelan 2/4 mg-Tabletten |
| - Netherlands | Tizagelan 2/4 mg tablets |
| - Finland | Tizagelan 2/4 mg tabletit |
| - Hungary | Tizagelan 2/4 mg tabletta |
| - Italy | Tizagelan 2/4 mg compresse |
| - Poland | Tizagelan |
| - United Kingdom | Tizagelan 2/4 mg tablets |

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