

PACKAGE LEAFLET

Package leaflet: Information for the user

Tizaflex 2 mg tablets

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

1. What Tizaflex is and what it is used for

- Tizaflex 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 Tizaflex

Do not take Tizaflex:

- if you are allergic to tizanidine or any of the other 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 Tizaflex', below).

Warnings and precautions

Talk to your doctor before taking Tizaflex

- if you have kidney problems.
- if you have heart problems such as coronary artery disease.
- if you have liver problems.

Other medicines and Tizaflex

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

Tizaflex must not be taken at the same time as fluvoxamine (to treat depression) or ciprofloxacin (an antibiotic) (see 'Do not take Tizaflex', above).

Tell your doctor or pharmacist if you are taking

- 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 Tizaflex 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's rhythm: check with your doctor or pharmacist.

Tizaflex with food, drink and alcohol

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

Pregnancy and breast-feeding

Tizaflex is not recommended for use during 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.

Driving and using machines

Tizaflex may cause drowsiness or dizziness (see '4. Possible side effects'). If you are affected do not drive or operate machinery.

Tizaflex contains lactose

This product 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 Tizaflex

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

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

Elderly

Your doctor will decide if you should take Tizaflex.

Use in children and adolescents (under 18 years)

Tizaflex is not recommended for use in children and adolescents.

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

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

The 4 mg tablet can be divided into equal doses

If you take more Tizaflex 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 Tizaflex

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 tablet.

If you stop taking Tizaflex

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

The following side effects have 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
- Nausea, 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):

- Inflammation of the liver (hepatitis) or liver failure, which may lead to yellowing of the eyes or skin and/or production of dark urine. Consult your doctor immediately if this occurs.

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

- Allergic reactions
- Blurred speech
- Stomach pain
- Vomiting
- Itching, rash
- Abnormal heart rhythms
- Headache, abnormal movements
- Difficulty focusing the eyes

- Loss of appetite
- Anxiety, confusion

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tizaflex

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 which is stated on the outer packaging. 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 Tizaflex contains

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

What Tizaflex looks like and contents of the pack

- Tizaflex is supplied in white, round tablets.
- Tizaflex 2 mg is marked 'N 62' on one side.
- Tizaflex 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 10, 28, 30, 34, 60, 84, 90, 91, 98, 100, 105 and 120 tablets.
- The 4 mg tablets are available in pack sizes of 10, 28, 30, 34, 60, 84, 90, 91, 98, 100, 105 and 120 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,
Euro House,
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Little Island,
Cork T45 K857,
Ireland

Manufacturer

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

United Kingdom	Tizanidine 2mg tablets, Tizanidine 4mg tablets
Ireland	Tizaflex 2mg tablets, Tizaflex 4mg tablets

This leaflet was last revised in November 2020