Package leaflet: Information for the user

Zanaflex® 2 mg tablets
Zanaflex® 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, pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zanaflex 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 Zanaflex
Do not take Zanaflex:
- 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 Zanaflex', below)

Warnings and precautions
Talk to your doctor or pharmacist before taking Zanaflex
- if you have **heart problems** such as coronary artery disease. Your doctor will check your heart function regularly using ECG.
- if you suffer from **severe weakness of certain muscles** (myasthenia gravis, leading to difficulty speaking, chewing and swallowing as well as drooping eyelids)
- if you suffer from epilepsy. Your disease must be well-controlled with medication.
- if you have kidney problems. Your doctor will adjust the dose of Zanaflex as needed. See section 3, "Patients with severe renal impairment".
- if you have **liver problems**, it may be necessary to have blood tests to monitor this. Zanaflex must not be taken in case of severe hepatic impairment. See section 4 'Possible side effects'.

Children and adolescents
Zanaflex is **not recommended** for use in children and adolescents below 18 years of age.

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- 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 Zanaflex if you are taking the pill.
- ticlopidine (to prevent blood clots)
- Rifampicin (an antibiotic)
- any medicine to treat high blood pressure, including diuretics (water tablets)
- antipsychotic medicines
- 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
- painkillers
- medicines that can be used to prevent pain by making the patient unconscious
- medicines used to relax muscles
- certain medicines to treat allergy or to prevent sickness
- any other medicines which, when taken with Zanaflex, might affect your heart's rhythm: check with your doctor or pharmacist.

Zanaflex with food, drink, alcohol and tobacco
Zanaflex can be taken independently of meals.
Alcohol may increase the sedative effect of Zanaflex. It is recommended not to drink alcohol while taking Zanaflex.
Smoking more than 10 cigarettes a day has shown a decrease in the effect of Zanaflex in men. Therefore, try to refrain from smoking.

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 for advice before taking this medicine.

A pregnancy test is recommended before treatment with Zanaflex for sexually active women who can become pregnant. Effective methods of contraception (birth control) during and up to one day after treatment with Zanaflex should be practiced. Ask your doctor about reliable methods of contraception.

Zanaflex is not recommended during pregnancy.
You should not breast-feed while you are taking Zanaflex.

Driving and using machines
Zanaflex may cause drowsiness or dizziness (see '4. Possible side effects'). Alcohol and sedatives may increase this effect. If you are affected do not drive or operate machinery.

Zanaflex 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 Zanaflex
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 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 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 Zanaflex.

Use in children and adolescents
Zanaflex is not recommended for use in children and adolescents.

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

Method of administration
Zanaflex is for oral use. The tablets should be swallowed with a glass of water.

This medicine can be taken with or without food.
The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

If you take more Zanaflex 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 Zanaflex
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 any extra tablets.

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

If you get any of the following serious side effects, stop taking Zanaflex and go to your doctor or to the nearest hospital straight away:
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. Nausea, stomach ache, poor appetite, feeling weak and unusual tiredness may also be signs.

Not known (frequency cannot be estimated from available data):
- Signs of allergic reactions such as skin rash, hives, lumps, redness, itching, maybe with swelling of the face, eyelids, and lips. This could additionally lead to difficulty in breathing, dizziness or shock.
- Feeling your heart is pounding or racing together with dizziness or fainting. This can be signs of serious heart rhythm problems and in severe cases may be fatal.
- Mental confusion.

Other possible side effects
Very common (may affect more than 1 in 10 people):
- Drowsiness, dizziness, tiredness
- Dry mouth, stomach upsets
- Muscle weakness

Common (may affect up to 1 in 10 people):
- Sleep disorders including difficulty in sleeping
- Decrease or increase in heart rate
- Reduction in blood pressure
- Feeling sick
- Changes in the function of the liver
- Increase of blood pressure or racing heartbeat when stopping the treatment. See section 3 ‘If you stop taking Zanaflex’.

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

Not known (frequency cannot be estimated from available data):
- Anxiety
- Headache
- Inability to co-ordinate muscle movements
- Difficulty speaking
- Blurred vision, difficulty focusing the eyes
- Fainting
- Stomach pain
- Vomiting
- Inflammation of the skin, reddening of the skin
- Loss of appetite
- Weakness

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 Zanaflex

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 blister and carton after EXP. The expiry date refers to the last day of that month. Do not store above 30 °C.
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 Zanaflex 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, silica, colloidal anhydrous.

What Zanaflex looks like and the contents of the pack
- Zanaflex 2 mg Tablets: White to off-white, biconvex, round tablets, 6 mm diameter, debossed “T2” on one side and scoreline on the other.
- Zanaflex 4 mg Tablets: White to off-white, biconvex, round tablets, 9 mm diameter, debossed “T4” on one side and quadrisected by scorelines on the other.

The 2 mg tablets are available in pack sizes of 120. The 4 mg tablets are available in pack sizes of 120.

Manufacturer
TEVA Pharmaceutical Works Private Limited Company (Batch release), Pallagi út 13, 4042 Debrecen, Hungary

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:
PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation number: PPA 465/474/1-2

Zanaflex is a registered trademark of Cephalon (UK) Limited.

This medicine is authorised in the Member States of the European Economic Area under the following names:

Bulgaria:	Zanaflex-Teva 2 mg таблетки
Bulgaria:	Zanaflex-Teva 4 mg таблетки
Germany:	Tizanidin-TEVA 2 mg Tabletten
Germany:	Tizanidin-TEVA 4 mg Tabletten
Denmark:	Tizanidin-Teva 2 mg Tabletter
Denmark:	Tizanidin-Teva 4 mg Tabletter
Ireland:	Zanaflex 2 mg Tablets
Ireland:	Zanaflex 4 mg Tablets
Portugal:	Tizanidina Teva
Portugal:	TizaniTeva

This leaflet was last revised in October 2022.