

ZANAFLEX 2 mg TABLETS
ZANAFLEX 4 mg TABLETS
Tizanidine

**PACKAGE LEAFLET:
 INFORMATION FOR THE USER**

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
2. What you need to know before you take Zanaflex
3. How to take Zanaflex
4. Possible side effects
5. How to store Zanaflex
6. Contents of the pack and other information

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

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)
- 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 Zanaflex, might affect your heart's rhythm: check with your doctor or pharmacist.

Zanaflex with food and drink and alcohol

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.

Pregnancy and breast-feeding

It is not recommended to take Zanaflex during pregnancy or whilst 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.

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.

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.

Pharma Code

Pharma Code

Pharma Code

Pharma Code

TEVA Design Department Harlow

Product: Zanaflex (Tizanidine) 2 & 4 mg Tabs All (TPW) TEI	Colours: Cutter Guide ■ PMS Process Black ■ PMS Green ■	Fonts: (Artwork) Body: Univers 55 Roman/ 65 Bold/ 55 Oblique 8pts Subhead: Univers 65 Bld 10pts Header: Univers 65 Bld 12pts	Amends: Draft: 1 Rev date: 19-4-16 Reviser: SD	Approval: Artwork Planner Signed _____ Date _____ <input type="checkbox"/> • Subject to Reg. Agency approval <input type="checkbox"/> • Approved by Reg. Dept. for print Signed _____ Date _____
Job No: 44118 SAP No: -		Software used: Indesign CS6	Artworker's Signature: _____	
Designer: SD Date: 18-4-16	Tints used:	100% Scale: 0 10 20 30 40 50 60 70 80 90 100 mm		
Component: Leaflet		Supplier Instructions Artwork, text and content must NOT be altered. The only exceptions to this are: bleeds, chokes, spreads or other adjustments required for print reproduction purposes only. If you have any difficulties please contact the Teva Artwork Team. We must receive a copy of the 3rd Party Vendors Proof before final approval can be made.		
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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 at the approximate frequencies shown:

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, nausea, stomach upsets
- Decrease or increase in heart rate

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

- Hallucinations
- Sleep disorders including difficulty in sleeping
- Allergic reactions (itching, rash)
- 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 available data):

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

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie;

E-mail: medsafety@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 4mg of tizanidine (as hydrochloride).
- The other ingredients are lactose anhydrous, cellulose microcrystalline, stearic acid and 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 quadrisectioned by scorelines on the other.
- The 2 mg tablets are available in pack sizes of 15, 20, 30, 50, 100, 120 & 500.
- The 4 mg tablets are available in pack sizes of 20, 30, 50, 100, 120, 200 & 500.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva Pharma B.V., Swensweg 5, 2031GA Haarlem, The Netherlands

Manufacturer

TEVA UK Ltd
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Company (Batch release) Táncsics Mihály út 82,
H-2100 Gödöllő

Pallagi út 13, 4042 Debrecen Hungary

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

UK	Tizanidine 2 mg Tablets
UK	Tizanidine 4 mg Tablets
AT	Tizanidin Teva 2 mg Tabletten
AT	Tizanidin Teva 4 mg Tabletten
BG	Tizanidine-Teva 2 mg таблетки
BG	Tizanidine-Teva 4 mg таблетки
DE	Tizanidin-TEVA 2 mg Tabletten
DE	Tizanidin-TEVA 4 mg Tabletten
DK	Tizanidin-Teva 2 mg Tabletter
DK	Tizanidin-Teva 4 mg Tabletter
EE	Tizanidine-Teva
EE	Tizanidine-Teva
FI	Tizanidin Teva 2 mg tabletti
FI	Tizanidin Teva 4 mg tabletti
IE	Zanaflex 2 mg Tablets
IE	Zanaflex 4 mg Tablets
IT	Tizanidina Teva 2 mg compresse
IT	Tizanidina Teva 4 mg compresse
LT	Tizanidine-Teva 2 mg tabletės
LT	Tizanidine-Teva 4 mg tabletės
LV	Tizanidine-Teva
LV	Tizanidine-Teva
PT	Tizanidina Teva
PT	TizaniTeva
SI	Tizanidina Teva 2mg tablete
SI	Tizanidina Teva 4mg tablete

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