PACKAGE LEAFLET: INFORMATION FOR THE USER

ZANAFLEX® 2mg Tablets
ZANAFLEX® 4mg 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 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.

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, Dublin 2, Ireland; 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 25°C. Store in the original package. 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
Each ZANAFLEX 2 mg tablet contains 2 mg of tizanidine (as hydrochloride) as the active ingredient.
Each ZANAFLEX 4 mg tablet contains 4 mg of tizanidine (as hydrochloride) as the active ingredient.
The other ingredients are colloidal anhydrous silica, stearic acid, microcrystalline cellulose and lactose anhydrous.
What ZANAFLEX looks like and contents of the pack
Zanaflex is supplied as white, circular, flat tablets, plain on one face and engraved with ‘Z’, a breakline and ‘O’ on the other face (for the 2mg tablets).” and “Zanaflex is supplied as white, circular, flat tablets, cross-scored on one side and engraved with R L on the other side (for the 4mg tablets).

Pack sizes of 30 tablets.

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

Parallel Product Authorisation Numbers:
Zanaflex 2mg Tablets - PPA 465/168/1
Zanaflex 4mg Tablets - PPA 465/168/2

MANUFACTURER
Zanaflex Tablets are manufactured by Novartis Pharma B.V., Raapopseweg 1, 6824 DP ARNHEM,
The Netherlands

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

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 Zanafl ex 2 mg Tablets
IE Zanafl ex 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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