

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.

- 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. Do not pass it on to others. It may harm them, even if their symptoms 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.

In this leaflet:

1. What ZANAFLEX is and what it is used for.
2. Before you use ZANAFLEX.
3. How to use ZANAFLEX.
4. Possible side effects.
5. How to store ZANAFLEX.
6. Further information.

1. WHAT ZANAFLEX IS AND WHAT IT IS USED FOR

The name of this medicine is ZANAFLEX. The active ingredient is tizanidine hydrochloride which belongs to a group of medicines called muscle relaxants. ZANAFLEX is used to relax muscles which have become stiff due to multiple sclerosis or other diseases affecting the spinal cord.

2. BEFORE YOU TAKE ZANAFLEX

Do not take ZANAFLEX if you:

- Are **allergic** (hypersensitive) to tizanidine hydrochloride or any of the other ingredients in ZANAFLEX.
 - Have liver problems.
 - Are taking a medicine called fluvoxamine or ciprofloxacin.
- ZANAFLEX is not suitable for children or the elderly.

Take special care with ZANAFLEX if you have:

- An intolerance to certain sugars (lactose and cellulose).
- Kidney problems.

If any of the above apply to you, you should speak to your doctor before taking this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken, any other medicines, including medicines obtained without a prescription. This is especially important if you are taking any of the following:

- The oral contraceptive pill.
- **Antibiotics** called norfloxacin, enoxacin or rifampicin.
- Ticlopidine to thin the blood.
- Cimetidine for stomach ulcers.
- Medicines which may make you drowsy e.g. sedatives (such as diazepam or temazepam), baclofen or antihistamines.

- Medicines **for high blood pressure** (e.g. water tablets, beta-blockers or clonidine).
- Medicines for **abnormal heart rhythms** e.g. digoxin, amiodarone, mexiletine or propafenone.
- Medicines that could affect the electrical rhythm of your heart (QT prolongation, for example amitriptyline and azithromycin).

Taking ZANAFLEX if you are a smoker

You should also tell your doctor if you are a smoker as this may mean you require a higher dose of ZANAFLEX for it to work properly.

Taking ZANAFLEX with food and drink

Alcohol may increase the chance of you feeling drowsy or experiencing side effects while taking ZANAFLEX. You should not drink alcohol with ZANAFLEX, consult your doctor before taking alcohol with ZANAFLEX.

Pregnancy and breast-feeding

ZANAFLEX is not recommended for use during pregnancy and breast-feeding. If you are pregnant, think you might be pregnant, are planning to become pregnant, or are breast-feeding tell your doctor or pharmacist before you take this medicine.

Driving and operating machinery

ZANAFLEX can sometimes cause blurred vision, drowsiness or dizziness in some people. If you are affected you should not drive or operate machinery.

Important information about some of the ingredients of ZANAFLEX

ZANAFLEX contains lactose and cellulose which are types of sugars. If you have been told you have an intolerance to some sugars contact your doctor before taking this medicine.

3. HOW TO TAKE ZANAFLEX

Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will usually start treatment with one 2 mg tablet once a day, but may instruct you to gradually increase the number of tablets you take and spread them out over the day. The exact dose will depend on your response to the tablets.

The total dose should not exceed 36 mg.

In patients with kidney disease the dose may be increased more slowly and you may need blood tests to check on your kidneys.

If you take more ZANAFLEX than you should

If you take too much ZANAFLEX you should contact your doctor or go to the nearest hospital emergency department immediately. Take the packet and this leaflet with you so that the doctor will know what you have taken.

If you forget to take ZANAFLEX

If you forget to take your dose in the morning you should take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten one.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ZANAFLEX can cause side effects, although not everyone gets them.

You should tell your doctor immediately if you experience signs of **liver damage** such as dark urine or yellowing of the eyes or skin or signs of an **allergic reaction** such as swelling of the face, lips or tongue, sudden wheezing, itching or nettle rash.

Other side effects include:

Very common side effects (affecting more than 1 in 10 patients)

- Drowsiness, feeling tired, weak muscles
- Dry mouth, stomach problems
- Dizziness

Common side effects (affecting 1 to 10 patients in 100)

- Difficulty in sleeping or problems whilst sleeping
- Low blood pressure
- Feeling sick
- Abnormal liver tests (this may be found on a blood test)

Uncommon side effects (affecting 1 to 10 patients in 1000)

- Slower heart rate

The following side effects have also been reported with the use of ZANAFLEX but it is not known how often they occur: Hallucinations, feeling confused, vertigo (a feeling of dizziness or spinning), loss of consciousness, inflammation of the liver, a feeling of weakness and blurred vision.

If any of the side effects become serious or you notice any side effects which are not listed in this leaflet, please tell your doctor or pharmacist.

If you stop taking ZANAFLEX:

The following side effects have been observed when patients stop taking ZANAFLEX suddenly after a long period of time, especially in patients on a high dose of ZANAFLEX or patients who take ZANAFLEX with drugs used to lower blood pressure: high blood pressure, increased heart rate (which may result in headache, blurred vision). Talk to your doctor before stopping treatment with ZANAFLEX.

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. See section 4. 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 out of the reach and sight of children.

Keep the tablets in the pack and do not use after the expiry date stated on the pack. There are no special precautions for storage

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures help protect the environment.

6. FURTHER 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. It also contains colloidal anhydrous silica, stearic acid, microcrystalline cellulose and lactose anhydrous as the inactive ingredients.

What ZANAFLEX looks like and contents of the pack

ZANAFLEX is supplied as white, round tablets marked with "A" and "592" (for the 2 mg tablets) or "A" and "594" (for the 4 mg tablets).

The tablets come in blister strips of 20 tablets and each packet contains 6 blister strips to give a packet size of 120 tablets.

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