

## Information For Patients Guide

### Zanaflex [ZAN'-a-flex] Capsules ® (tizanidine hydrochloride)

**You must read and follow all instructions before using Zanaflex Capsules®.**

Read the Information For Patients Guide you get every time you or a family member gets Zanaflex Capsules. There may be new information. This Information for Patients Guide does not take the place of talking with your doctor about your medical condition or treatment. If you have any questions about Zanaflex Capsules, ask your doctor or pharmacist.

#### **What is the most important information I should know about Zanaflex Capsules?**

- The safety of using Zanaflex Capsules for longer than 1 year or at doses higher than those recommended (more than 8 mg at a time, or more than 24 mg in a day) is not known.
- Zanaflex Capsules are not the same as generic tizanidine tablets or Zanaflex (tizanidine hydrochloride) tablets. You may have different side effects if you switch from capsules to tablets. **Talk to your doctor if your prescription is changed from capsules to tablets.**
- Whether you take Zanaflex Capsules with or without food may effect the way the medication works and possible side effects. Also, whether or not you open the capsule and sprinkle the medicine on food can effect how the medication works and possible side effects. **Follow your doctor's instructions on how to take your medicine.**
- Zanaflex Capsules may cause a decrease in your blood pressure that can cause dizziness, lightheadedness, or fainting when you rise suddenly from a sitting or lying position. Rising slowly may decrease the risk of these problems.
- You may have drowsiness when taking Zanaflex Capsules. Do not drive or operate heavy equipment. Alcohol and certain medicines (such as antihistamines, sedatives, tranquilizers, sleeping medicines, prescription pain medicines, narcotics, anti-epileptics, or other muscle relaxants) may increase the drowsiness you have with Zanaflex Capsules. **Tell your doctor about all your medical conditions and all the medicines you take including prescription and nonprescription medicines.**
- Since this medication can decrease the spasticity (tone) of your muscles, be careful when using Zanaflex Capsules if your spasticity helps you with posture or balance.
- Do not stop taking Zanaflex Capsules suddenly, since rapid changes in heart rate or blood pressure may occur. **Follow your doctor's instructions for stopping therapy with Zanaflex Capsules.**
- You should not take Zanaflex Capsules if you are currently taking fluvoxamine (Luvox®), ciprofloxacin (Cipro®) or clonidine (Catapres® and Catapres TTS®), or if you have kidney damage.

- Rare cases of liver damage have been reported in patients using tizanidine hydrochloride. **Tell your doctor if you have had moderate or severe liver problems, including problems while taking other medicines.**
- Rare cases of hallucinations (seeing things that weren't there) have been reported in patients receiving tizanidine hydrochloride. **Tell your doctor immediately if you experience hallucinations.**

## What are Zanaflex Capsules?

Zanaflex Capsules are a short-acting drug for the management of spasticity. Spasticity can be associated with medical conditions such as multiple sclerosis, spinal cord injury, traumatic brain injury or stroke.

Zanaflex Capsules are available in 3 different strengths: 2 mg, 4 mg and 6 mg.

## Who should not use Zanaflex Capsules?

### Do not use Zanaflex Capsules:

- If you are currently taking fluvoxamine (Luvox®), ciprofloxacin (Cipro®) or clonidine (Catapres® and Catapres TTS®).
- If you are allergic to Zanaflex Capsules or anything in it. See the end of this Information For Patients Guide for a complete list of ingredients. Stop taking the drug and contact your doctor immediately if you experience an allergic reaction or any severe or unusual side effects.
- If your blood tests show possible liver damage.
- If you have kidney damage.

**Tell your doctor about all of your medical conditions and all the prescription and nonprescription medicines you take.** Zanaflex Capsules and other medicines may affect each other causing side effects. Do not start any new medicines until you check with your doctor.

Zanaflex Capsules have not been studied in children.

Zanaflex Capsules have not been studied in pregnant women.

## How should I use Zanaflex Capsules?

- Use Zanaflex Capsules exactly as your doctor tells you to. During the first weeks of treatment, your doctor may want to adjust your dose to meet your individual needs.
- Whether you take Zanaflex Capsules with food or without food may affect the way the medicine works and possible side effects. **Follow your doctor's instructions on how to take your medicine.**

- If you have difficulty swallowing, Zanaflex Capsules can be opened and sprinkled on soft foods such as applesauce. **Because the effects of the medication can be different than when taking the whole capsule, talk with your doctor before you open the capsule.**
- If you forget to take your medicine you should contact your doctor. If you forget a dose completely, do not take two doses at the same time. Be sure to ask your doctor about how to take your medication.
- Call your doctor if:
  - You take more than your regular dose of Zanaflex Capsules
  - You become pregnant

### **What should I avoid while using Zanaflex Capsules?**

- Do not switch between using Zanaflex Capsules and generic tizanidine (tizanidine hydrochloride) tablets or Zanaflex tablets without receiving instructions from your doctor.
- Do not stop taking Zanaflex Capsules suddenly, since sudden changes in heart rate or blood pressure may occur. Talk to your doctor about stopping medication.
- Follow your doctor's instructions as to whether to take Zanaflex Capsules with or without food.
- Avoid driving a car or operating heavy machinery until you know whether Zanaflex Capsules cause sleepiness or drowsiness. Alcohol and certain medicines (such as antihistamines, sedatives, tranquilizers, sleeping medicines, prescription pain medicines, narcotics, anti-epileptics, or other muscle relaxants) may increase the drowsiness you have with Zanaflex Capsules.
- Avoid rising rapidly from a seated or lying down position if you have dizziness while using Zanaflex Capsules.
- Since this medication can decrease the spasticity (tone) of your muscles, be careful when using Zanaflex Capsules if your spasticity helps you with posture or balance.

### **What are the possible side effects of Zanaflex Capsules?**

#### **Serious side effects of Zanaflex Capsules include:**

- **Low Blood Pressure** Zanaflex Capsules may cause a decrease in your blood pressure that can cause dizziness, lightheadedness, or fainting when you rise suddenly from a sitting or lying position. Rising slowly may decrease the risk of these problems.
- **Rare reports of Liver Damage** Tell your doctor if you have had moderate or severe liver problems, including problems while taking other medicines.

- **Rare cases of hallucinations** (seeing things that weren't there) Tell your doctor immediately if you experience hallucinations.
- **The most common side effects of Zanaflex Capsules include:**
  - Dry mouth
  - Drowsiness
  - Weakness, fatigue and/or tiredness
  - Dizziness

These are not all the side effects associated with Zanaflex Capsules. Ask your doctor or pharmacist for more information.

### **How should I store Zanaflex Capsules?**

- Store Zanaflex Capsules at room temperature between 59° to 86° F (15° to 30° C).
- **Keep Zanaflex Capsules and all medicines out of the reach of children and store in containers with child resistant caps**

### **General advice about Zanaflex Capsules**

Medicines are sometimes prescribed for purposes other than those listed in an Information Guide for Patients. Use Zanaflex Capsules only for the condition for which it was prescribed. Do not give Zanaflex Capsules to other people even if they have the same symptoms you have, as it may not be right for them.

This Information For Patients Guide summarizes important information about Zanaflex Capsules. Please see the full prescribing information (attached to this document) for more information. If you need more information, please talk with your doctor.

Your doctor or pharmacist can give you information about Zanaflex Capsules that is written for health care professionals. For more information, you can visit the Acorda Therapeutics website at [www.zanaflexcapsules.com](http://www.zanaflexcapsules.com) or call the Acorda Medical Information System toll-free at 800-367-5109.

### **What are the ingredients in Zanaflex Capsules?**

**Active ingredient:** Tizanidine hydrochloride

**Inactive ingredients:** hydroxypropyl methyl cellulose, silicon dioxide, sugar spheres, titanium dioxide, gelatin, and colorants.

Manufactured by: Distributed by:  
Acorda Therapeutics  
Hawthorne, NY 10532  
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