

## Medication Guide

### TUZISTRA<sup>®</sup> XR (two-zis-tra)

(codeine polistirex and chlorpheniramine polistirex) extended-release oral suspension, C-III

#### What is the most important information I should know about TUZISTRA XR?

- Taking TUZISTRA XR with benzodiazepines, or other central nervous system depressants, including alcohol can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.
- TUZISTRA XR can cause you to be drowsy. Avoid driving a car or operating machinery during treatment with TUZISTRA XR.
- **Do not** give TUZISTRA XR to a child to treat pain after tonsillectomy or adenoidectomy surgery.
  - When you take TUZISTRA XR, some of it changes into morphine in your body.
  - In some children and adults this happens very quickly, and can cause you to stop breathing and cause death due to an overdose.
- Women who breastfeed should talk to their healthcare provider before taking TUZISTRA XR.
  - When you take TUZISTRA XR, some of it changes into morphine in your body.
  - In some women, this happens very quickly. Codeine and morphine pass into your breast milk. A large amount of morphine can cause your baby to die.
- Call your healthcare provider or get emergency medical help right away if anyone taking TUZISTRA XR, or your breastfeeding baby has any of the symptoms listed below:
  - increased sleepiness
  - confusion
  - difficulty breathing
  - shallow breathing
  - limpness
  - your baby has difficulty breastfeeding
- Keep TUZISTRA XR in a safe place away from children. Accidental use by a child is a medical emergency and can cause death. If a child accidentally takes TUZISTRA XR, get emergency help right away.
- TUZISTRA XR can cause serious side effects, including death.
- Take TUZISTRA XR exactly as prescribed by your healthcare provider. If you take the wrong dose of TUZISTRA XR, you could overdose and die.
- It is especially important when you take TUZISTRA XR that you know exactly what dose to take.

#### What is TUZISTRA XR?

- TUZISTRA XR is a prescription medicine used to treat cough and upper respiratory symptoms that you can have with allergies or a common cold. TUZISTRA XR is for adults 18 years and older. TUZISTRA XR contains 2 medicines, codeine and chlorpheniramine. Codeine is a narcotic cough suppressant. Chlorpheniramine is an antihistamine.
- **TUZISTRA XR is a federal controlled substance (C-III) because it contains codeine that can be abused or lead to dependence.** Keep TUZISTRA XR in a safe place to prevent misuse and abuse. Selling or giving away TUZISTRA XR may harm others, and is against the law. Tell your healthcare provider if you have abused or been dependent on alcohol, prescription medicines or street drugs.
- TUZISTRA XR is not for children under 18 years of age. It is not known if TUZISTRA XR is safe and effective in children.

#### Who should not take TUZISTRA XR?

- **Do not** give TUZISTRA XR to a child to treat pain after tonsillectomy or adenoidectomy surgery.
- **Do not** take TUZISTRA XR if you are allergic to any of the ingredients in TUZISTRA XR. See the end of this Medication Guide for a complete list of ingredients in TUZISTRA XR. You may have an increased risk of having an allergic reaction to TUZISTRA XR if you are allergic to certain other opioid medicines.

#### Before you take TUZISTRA XR, tell your healthcare provider about all your medical conditions, including if you:

- have a drug dependence
- have lung or breathing problems
- have had a head injury
- have pain in your stomach-area (abdomen)
- have a history of severe or persistent cough
- have prostate problems
- are pregnant or plan to become pregnant. It is not known if TUZISTRA XR will harm your unborn baby. You and your healthcare provider should decide if you should take TUZISTRA XR while you are pregnant.
- are breastfeeding or plan to breastfeed. Codeine and chlorpheniramine pass into your breast milk and may harm your baby. You and your healthcare provider should discuss whether you should take TUZISTRA XR or breastfeed. You should not do both.
- have problems with your urinary tract (urethral stricture)
- plan to have surgery
- drink alcohol
- have kidney or liver problems
- have diabetes
- have thyroid problems, such as hypothyroidism

**Tell your healthcare provider about all of the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking TUZISTRA XR with certain other medicines can cause side effects or affect how well TUZISTRA XR or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

**Especially tell your healthcare provider if you:**

- take pain medicines such as narcotics
- take cold or allergy medicines that contain antihistamines or cough suppressants
- take medicines for mental illness (anti-psychotics, anti-anxiety)
- drink alcohol
- take medicines for depression including monoamine oxidase inhibitors (MAOIs)
- take medicines for stomach or intestine problems

Ask your healthcare provider if you are not sure if you take one of these medicines.

**How should I take TUZISTRA XR?**

- Take TUZISTRA XR exactly as your healthcare provider tells you.
- Your healthcare provider will tell you how much TUZISTRA XR to take and when to take it. Do not change your dose without talking to your healthcare provider.
- TUZISTRA XR is usually taken every 12 hours.
- **Do not** take more than 20 mL of TUZISTRA XR in 24 hours.
- Take TUZISTRA XR by mouth only.
- Shake the TUZISTRA XR bottle well before you use it.
- TUZISTRA XR can be taken with or without food.
- **Do not** mix TUZISTRA XR with other fluids or medicines.
- TUZISTRA XR should be taken using an accurate milliliter measuring device.
- Ask your pharmacist to give you a measuring device to help you measure the correct amount of TUZISTRA XR. **Do not use a household teaspoon to measure your medicine. You may accidentally take too much.**
- If you take too much TUZISTRA XR, call your healthcare provider or go to the nearest hospital emergency room right away.

**What should I avoid doing while taking TUZISTRA XR?**

- TUZISTRA XR can cause you to be drowsy. Avoid driving a car or using machinery during treatment with TUZISTRA XR.
- Avoid drinking alcohol during treatment with TUZISTRA XR. Drinking alcohol can increase your chances of having serious side effects.

**What are the possible side effects of TUZISTRA XR?**

**TUZISTRA XR may cause serious side effects, including:**

- See “**What is the most important information I should know about TUZISTRA XR?**”
- **Breathing problems** (respiratory depression) which can lead to death. Call your healthcare provider or get emergency treatment right away if you have excessive sleepiness, shallow or slow breathing, or confusion.
- **Physical dependence or abuse.** Take TUZISTRA XR exactly as your healthcare provider tells you to take it. Stopping TUZISTRA XR suddenly could cause withdrawal symptoms.
- **Increased intracranial pressure.**
- **Bowel problems** including constipation or stomach pain.

**The most common side effects of TUZISTRA XR include:**

- |   |                        |  |
|---|------------------------|--|
| • nausea and vomiting   | • dizziness            | • general feeling of discomfort or illness |
| • constipation swelling or bloating of your stomach-area      | • depression           | • unable to control muscle movements       |
| • stomach-area pain   | • drowsiness           | • excitability, nervousness                |
| • vision problems, including blurred vision and double-vision | • headache             | • agitation, restlessness, irritability    |
| • confusion   | • feel high (euphoria) | • sleepiness                               |
|   | • feeling faint        | • difficulty sleeping (insomnia)           |
|   | • lightheadedness      | • tremor                                   |

These are not all the possible side effects of TUZISTRA XR.

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

**How should I store TUZISTRA XR?**

- Store TUZISTRA XR in a safe place between 68°F to 77°F (20°C to 25°C).
- Keep TUZISTRA XR in a tightly closed, child-resistant container and out of the light.
- Safely throw away medicine that is out of date or no longer needed.
- **Keep TUZISTRA XR and all medicines out of the reach of children.**

**General information about the safe and effective use of TUZISTRA XR:**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TUZISTRA XR for a condition for which it was not prescribed. Do not give TUZISTRA XR to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about TUZISTRA XR that is written for health professionals.

**What are the ingredients in TUZISTRA XR?**

**Active ingredients:** codeine and chlorpheniramine.

**Inactive ingredients:** cherry flavor, citric acid, D&C Red No. 30, ethyl maltol, glycerin, methylparaben, polysorbate 80, polyvinyl acetate, povidone, propyl gallate, propylparaben, purified water, sodium citrate, sodium polystyrene sulfonate, starch, sucrose, triacetin, xanthan gum

Manufactured by: Tris Pharma, Inc.; Monmouth Junction, NJ 08852, Manufactured for and Distributed by: Vernalis Therapeutics, Inc.; Berwyn, PA 19312

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For more information, go to [www.vernalistherapeutics.com](http://www.vernalistherapeutics.com) or call 1-855-705-9546

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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