

# HOW DISRUPTIVE IS YOUR COUGH TODAY?

This questionnaire is designed to assess the impact of cough on various aspects of your life. Answer each question by CIRCLING the response that best applies to you.

0 Never      1 Rarely      2 Sometimes      3 Often      4 Always

> My cough disrupts my daily activities	0 1 2 3 4
> My cough disrupts my sleep	0 1 2 3 4
> My cough interferes with the overall enjoyment of my life	0 1 2 3 4
> I feel an urge to cough in my throat or chest that precedes my cough	0 1 2 3 4
> My cough is severe	0 1 2 3 4
> My cough is not controlled by home remedies or other cough-cold treatments	0 1 2 3 4
> Other cold or allergy-like symptoms, such as sore throat, runny/stuffy/itchy nose, sneezing, itchy/watery eyes, etc., make my cough worse	0 1 2 3 4

Total your score: \_\_\_\_\_



**Tuzistra<sup>®</sup>XR** III  
 (Codeine Polistirex and  
 Chlorpheniramine Polistirex)  
 EXTENDED-RELEASE ORAL SUSPENSION

**The higher your score,  
 the more disruptive your cough.**  
 Ask your physician about  
 12-hour prescription cough syrup.

## What is TUZISTRA<sup>®</sup> XR (codeine polistirex and chlorpheniramine polistirex) extended-release oral suspension, CIII?

TUZISTRA XR (two-zis-tra) is a prescription medicine that contains codeine (a narcotic cough suppressant) and chlorpheniramine (an antihistamine) and is used for the relief of cough and symptoms associated with upper respiratory allergies or a common cold. TUZISTRA XR is for adults 18 years and older.

TUZISTRA XR is a controlled substance (CIII) because it contains codeine that can be abused or lead to dependence. Keep your TUZISTRA XR in a safe place to prevent misuse and abuse. Never give your TUZISTRA XR to anyone else, because it may cause death or harm them. Selling or giving away this medicine is against the law.

### **WARNING: DEATH RELATED TO ULTRA-RAPID METABOLISM OF CODEINE TO MORPHINE and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS**

**Ultra-Rapid Metabolism:** Respiratory depression and death have occurred in children who received codeine following tonsillectomy and/or adenoidectomy and had evidence of being ultra-rapid metabolizers of codeine due to a CYP2D6 polymorphism.

**Concomitant Use with Benzodiazepines, CNS Depressants:** Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Avoid use of opioid cough medications in patients taking benzodiazepines, other CNS depressants, or alcohol.

See additional Important Safety Information on reverse side and the Medication Guide at [www.tuzistraxr.com](http://www.tuzistraxr.com).

## IMPORTANT RISK INFORMATION

### What is the most important information I should know about Tuzistra XR extended-release oral suspension?

- 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 die due to an overdose.
- Women who breastfeed should talk to their healthcare provider before taking TUZISTRA XR. Codeine and morphine pass into your breastmilk, and 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
  - shallow breathing
  - confusion
  - limpness
  - difficulty breathing
  - 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.

### 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.

### What should I tell my healthcare professional before taking TUZISTRA XR?

Before you take TUZISTRA XR, tell your healthcare professional if you:

- Have a drug dependence or abuse alcohol
- Have problems with your urinary tract (eg, urethral stricture)
- Have lung or breathing problems
- Plan to have surgery
- Have had a head injury, pain in your stomach (abdomen), kidney or liver problems, a history of severe or persistent cough, diabetes, prostate or thyroid problems (such as hypothyroidism)
- Are pregnant or breastfeeding, or plan to become pregnant or breastfeed

Tell your healthcare professional about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. **Especially tell your healthcare professional if you take medicines for:**

- Pain (such as narcotics)
- Cold or allergy (antihistamines or cough suppressants)
- Mental illness (anti-psychotics, anti-anxiety) or depression, including monoamine oxidase inhibitors (MAOIs)
- Stomach or intestine problems.

### 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:

- **Decreased breathing (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 are: nausea and vomiting, dizziness, general feeling of discomfort or illness, constipation, bloating, and depression.

Other side effects include: inability to control muscle movements, drowsiness, excitability, nervousness, stomach pain, headache, agitation, restlessness, irritability, vision problems, including blurred vision and double-vision, feeling high (euphoria), sleepiness, feeling faint, difficulty sleeping (insomnia), confusion, lightheadedness, and tremor.

These are not all the possible side effects of TUZISTRA XR. For more information, ask your doctor or pharmacist. Tell your healthcare professional if you have any side effect that bothers you or does not go away.

Read the TUZISTRA XR Patient Information before you start taking TUZISTRA XR and each time you get a refill, as there may be changes. This information does not take the place of talking to your healthcare professional about your medical condition or treatment.

**You are encouraged to report negative side effects of prescription drugs to the FDA.**

**Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

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