

TuxarinERTM

(codeine phosphate and chlorpheniramine maleate extended-release tablets)



Tuxarin ERTM is indicated for the relief of cough and symptoms associated with upper respiratory allergies or a common cold in adults 18 years of age and older.

INGREDIENTS PER TABLET

54.3mg codeine phosphate, equivalent to 40mg of codeine, and 8mg chlorpheniramine maleate equivalent to 5.6mg of chlorpheniramine.

DOSING

One tablet every 12 hours (not to exceed 2 doses in 24 hours).

HOW SUPPLIED

Bottles of 30 tablets: NDC # 71269-040-30

Bottles of 100 tablets: NDC # 71269-040-10

POINTS OF DIFFERENTIATION

- Tuxarin ERTM is the only FDA-approved extended-release tablet containing codeine and chlorpheniramine
- Tuxarin ERTM as a CIII does not require DEA Form 222 to be submitted
- Unlike a CII, refills may be allowable for CIII prescriptions
- Some states allow for Nurse Practitioners to write CIII prescriptions
- Physicians may be able to phone in CIII prescriptions (not a CII option)
- Tuxarin ERTM can be taken with or without food



For more information, go to
www.mainpointepharmaceuticals.com
or call **502-709-7544**

WARNINGS AND PRECAUTIONS

- Overdose of codeine has been associated with fatal respiratory depression
- Tuxarin ERTM not indicated for children under 18 years of age
- Side Effects and Drug Interactions (on Package Insert/Medication Guide)
- Rx only; Pharmacist dispense Tuxarin ERTM with Medication Guide

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To report an adverse event, call: (800) FDA-1088

For full prescribing information, see www.tuxariner.com



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MEDICATION GUIDE

Tuxarin^{ER}™ (tuks a ren)

(codeine phosphate and chlorpheniramine maleate extended-release tablets)



What is the most important information I should know about TUXARIN ER?

- TUXARIN ER can cause children to stop breathing (respiratory depression) and cause death.
- Do not give TUXARIN ER to children younger than 12 years of age, or to children younger than 18 years of age after tonsillectomy or adenoidectomy surgery.
- You should not give TUXARIN ER to children between 12 to 18 years of age who have certain risk factors for breathing problems, including:
 - recent surgery
 - obstructive sleep apnea
 - are obese
 - severe lung problems
 - other medical conditions that can cause difficulty breathing, such as neuromuscular problems
 - taking other medicines that cause breathing problems
- You should not breastfeed during treatment with TUXARIN ER because it may cause your child to stop breathing and cause death.
- Severe drowsiness, breathing problems (respiratory depression), coma, and death can happen in adults and children who take TUXARIN ER with benzodiazepines, or other central nervous system depressants, including alcohol.
- Avoid taking other medicines that can cause drowsiness or sleepiness, or drinking alcohol during treatment with TUXARIN ER. Ask your healthcare provider for a list of these medicines if you are not sure.
- TUXARIN ER can cause breathing problems (respiratory depression) and drowsiness.
 - Take TUXARIN ER exactly as prescribed by your healthcare provider. If you take the wrong dose of TUXARIN ER, you could overdose and die. See the Medication Guide section called “How should I take TUXARIN ER?” for important information about how to take TUXARIN ER correctly.
- Avoid driving a car or operating machinery during treatment with TUXARIN ER.
- Call your healthcare provider or get emergency medical help right away if anyone taking TUXARIN ER, 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 TUXARIN ER 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 TUXARIN ER, get emergency help right away.

What is TUXARIN ER?

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

Who should not take TUXARIN ER?

- Do not give TUXARIN ER to any children younger than 12 years of age.
- Do not give TUXARIN ER to children younger than 18 years of age following tonsillectomy or adenoidectomy surgery.

- Do not take TUXARIN ER if you are allergic to any of the ingredients in TUXARIN ER. See the end of this Medication Guide for a complete list of ingredients in TUXARIN ER. You may have an increased risk of having an allergic reaction to TUXARIN ER if you are allergic to certain other opioid medicines.

Before taking TUXARIN ER, tell your healthcare provider about all of your medical conditions, including if you:

- have a drug dependence
- have problems with your urinary tract (urethral stricture)
- have lung or breathing problems
- plan to have surgery
- have had a head injury
- abuse alcohol
- have pain in your stomach (abdomen)
- have kidney or liver problems
- have constipation or problems with your intestines
- have thyroid problems, such as hypothyroidism
- have prostate problems
- have Addison's disease
- are pregnant or plan to become pregnant. It is not known if TUXARIN ER will harm your unborn baby. You and your healthcare provider should decide if you should take TUXARIN ER 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 TUXARIN ER or breastfeed. You should not do both.

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

Using TUXARIN ER with certain other medicines may affect each other. Using TUXARIN ER with other medicines can cause serious side effects.

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, other mental health problems, or Parkinson's disease, including monoamine oxidase inhibitors (MAOIs), or if you have taken an MAOI in the last 14 days
 - 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 TUXARIN ER?

- Take TUXARIN ER exactly as your healthcare provider tells you.
- Do not take more than 2 TUXARIN ER tablets in 24 hours.
- If you take too much TUXARIN ER, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking TUXARIN ER?

- TUXARIN ER can cause you to be drowsy. Avoid driving a car or using machinery during treatment with TUXARIN ER.
- Do not drink alcohol during treatment with TUXARIN ER. Drinking alcohol can increase your chances of having serious side effects.

What are the possible side effects of TUXARIN ER?

- TUXARIN ER may cause serious side effects, including:
- See “What is the most important information I should know about TUXARIN ER?”

- 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 TUXARIN ER exactly as your healthcare provider tells you to take it.
- Stopping TUXARIN ER suddenly could cause withdrawal symptoms.
 - Increased intracranial pressure
 - Bowel problems including constipation or stomach pain.

The most common side effects of TUXARIN ER include:

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

These are not all the possible side effects of TUXARIN ER. 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 TUXARIN ER?

- Store TUXARIN ER in a safe place between 68°F to 77°F (20°C to 25°C).
- Keep TUXARIN ER 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 TUXARIN ER and all medicines out of the reach of children.

General information about the safe and effective use of TUXARIN ER.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TUXARIN ER for a condition for which it was not prescribed. Do not give TUXARIN ER 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 TUXARIN ER that is written for health professionals.

What are the ingredients in TUXARIN ER?

Active ingredients: codeine and chlorpheniramine
Inactive ingredients: Hypromellose, lactose monohydrate, cellulose microcrystalline, polysorbate 80, magnesium stearate, and colloidal silicon dioxide.

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For more information go to mainpointepharmaceuticals.com or call 502-709-7544. This Medication Guide has been approved by the U.S. Food and Drug Administration.

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