

MEDICATION GUIDE
TUSSIONEX[®] Pennkinetic[®] (tuss-i-necks pen-ki-ne-tik)
(hydrocodone polistirex and chlorpheniramine polistirex)
Extended-Release Suspension CII

What is the most important information I should know about TUSSIONEX Pennkinetic Extended-Release Suspension?

- Taking TUSSIONEX Pennkinetic Extended-Release Suspension with benzodiazepines, or other central nervous system depressants, including alcohol can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.
- TUSSIONEX Pennkinetic Extended-Release Suspension can cause you to be drowsy. Avoid driving a car or operating machinery during treatment with TUSSIONEX Pennkinetic Extended-Release Suspension.
- Women who breastfeed should talk to their healthcare provider before taking TUSSIONEX Pennkinetic Extended-Release Suspension.
- Call your healthcare provider or get emergency medical help right away if anyone taking TUSSIONEX Pennkinetic Extended-Release Suspension has any of the symptoms below:
 - increased sleepiness
 - confusion
 - difficulty breathing
 - shallow breathing
 - limpness
 - your baby has difficulty breastfeeding
- Keep TUSSIONEX Pennkinetic Extended-Release Suspension 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 TUSSIONEX Pennkinetic Extended-Release Suspension, get emergency medical help right away.
- TUSSIONEX Pennkinetic Extended-Release Suspension can cause serious side effects, including death.
- Take TUSSIONEX Pennkinetic Extended-Release Suspension exactly as prescribed by your healthcare provider. If you take the wrong dose of TUSSIONEX Pennkinetic Extended-Release Suspension, you could overdose and die.
- TUSSIONEX Pennkinetic Extended-Release Suspension is not for children under 6 years of age.

What is TUSSIONEX Pennkinetic Extended-Release Suspension?

- TUSSIONEX Pennkinetic Extended-Release Suspension is a prescription medicine used to treat cough and upper respiratory symptoms that you can have with allergies or a cold. TUSSIONEX Pennkinetic Extended-Release Suspension is for adults and children age 6 years and older. TUSSIONEX Pennkinetic Extended-Release Suspension contains 2 medicines, hydrocodone and chlorpheniramine. Hydrocodone is a narcotic cough suppressant. Chlorpheniramine is an antihistamine.
- **TUSSIONEX Pennkinetic Extended-Release Suspension is a federal controlled substance (CII) because it contains hydrocodone that can be abused or lead to dependence.** Keep TUSSIONEX Pennkinetic Extended-Release Suspension in a safe place to prevent misuse and abuse. Selling or giving away TUSSIONEX Pennkinetic Extended-Release Suspension 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.
- TUSSIONEX Pennkinetic Extended-Release Suspension is not for children under 6 years of age.

Who should not take TUSSIONEX Pennkinetic Extended-Release Suspension?

- **Do not** take TUSSIONEX Pennkinetic Extended-Release Suspension if you are allergic to any of the ingredients in TUSSIONEX Pennkinetic Extended-Release Suspension. See the end of this Medication Guide for a complete list of ingredients. You may have an increased risk of having an allergic reaction to

MEDICATION GUIDE

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TUSSIONEX Pennkinetic Extended-Release Suspension if you are allergic to certain other opioid medicines.

- **Do not** give TUSSIONEX Pennkinetic Extended-Release Suspension to a child under 6 years of age. It can cause breathing problems that can lead to death.

Before you take TUSSIONEX Pennkinetic Extended-Release Suspension, tell your healthcare provider about all of 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 glaucoma
- have prostate problems
- 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
- Addison's disease
- are pregnant or plan to become pregnant. It is not known if TUSSIONEX Pennkinetic Extended-Release Suspension will harm your unborn baby. You and your healthcare provider should decide if you should take TUSSIONEX Pennkinetic Extended-Release Suspension while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if TUSSIONEX Pennkinetic Extended-Release Suspension passes into your breast milk. You and your healthcare provider should decide if you will take TUSSIONEX Pennkinetic Extended-Release Suspension or breastfeed. You should not do both.

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

Taking TUSSIONEX Pennkinetic Extended-Release Suspension with certain other medicines can cause side effects or affect how well TUSSIONEX Pennkinetic Extended-Release Suspension 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) and tricyclics
- 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 TUSSIONEX Pennkinetic Extended-Release Suspension?

- Take TUSSIONEX Pennkinetic Extended-Release Suspension exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much TUSSIONEX Pennkinetic Extended-Release Suspension to take and when to take it. Do not change your dose without talking to your healthcare provider.
- Shake TUSSIONEX Pennkinetic Extended-Release Suspension well before each use.

MEDICATION GUIDE

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- **Do not** mix TUSSIONEX Pennkinetic Extended-Release Suspension with other liquids or medicines. Mixing may change how TUSSIONEX Pennkinetic Extended-Release Suspension works.
- TUSSIONEX Pennkinetic Extended-Release Suspension can be taken with or without food.
- **Only measure TUSSIONEX Pennkinetic Extended-Release Suspension with the dosing spoon that comes with your prescription.** If you do not have a dosing spoon for your medicine, ask your pharmacist to give you a measuring device to help you measure the correct amount of TUSSIONEX Pennkinetic Extended-Release Suspension. **Do not use a household teaspoon to measure your medicine. You may accidentally take too much.**
 - One side of the dosing spoon is marked for a 2.5 mL dose. The other side of the spoon is marked for a 5 mL dose. Find the side of the spoon that has the dose you are taking.
 - Fill that side of the spoon so the medicine is level with the rim of the spoon. **Do not** overfill the spoon.
 - Rinse the spoon with water after each use.
- **If you take too much TUSSIONEX Pennkinetic Extended-Release Suspension, call your healthcare provider or go to the nearest hospital emergency room right away.**

What should I avoid while taking TUSSIONEX Pennkinetic Extended-Release Suspension?

- TUSSIONEX Pennkinetic Extended-Release Suspension can cause you to be drowsy. Avoid driving a car or operating machinery during treatment with TUSSIONEX Pennkinetic Extended-Release Suspension.
- Avoid drinking alcohol during treatment with TUSSIONEX Pennkinetic Extended-Release Suspension. Drinking alcohol can increase your chances of having serious side effects.

What are the possible side effects of TUSSIONEX Pennkinetic Extended-Release Suspension?

TUSSIONEX Pennkinetic Extended-Release Suspension may cause serious side effects, including:

- See "[What is the most important information I should know about TUSSIONEX Pennkinetic Extended-Release Suspension?](#)"
- **Breathing problems (respiratory depression) which can lead to death.** Call your healthcare provider or get emergency treatment right away if you are sleeping more than usual, have shallow or slow breathing, or confusion.
- **Increased intracranial pressure.**
- **Physical dependence or abuse.** Take TUSSIONEX Pennkinetic Extended-Release Suspension exactly as your healthcare provider tells you to take it. Stopping TUSSIONEX Pennkinetic Extended-Release Suspension suddenly can cause withdrawal symptoms.
- **Bowel problems including constipation or stomach pain.**

The most common side effects of TUSSIONEX Pennkinetic Extended-Release Suspension include:

- sleepiness
- confusion
- nausea and vomiting
- difficulty urinating
- trouble breathing

These are not all the possible side effects of TUSSIONEX Pennkinetic Extended-Release Suspension.

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

MEDICATION GUIDE
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How should I store TUSSIONEX Pennkinetic Extended-Release Suspension?

- Store TUSSIONEX Pennkinetic Extended-Release Suspension at room temperature between 68°F to 77°F (20°C to 25°C).
- Safely throw away medicine that is out of date or no longer needed.
- **Keep TUSSIONEX Pennkinetic Extended-Release Suspension and all medicines out of the reach of children.**

General information about the safe and effective use of TUSSIONEX Pennkinetic Extended-Release Suspension.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TUSSIONEX Pennkinetic Extended-Release Suspension for a condition for which it was not prescribed. Do not give TUSSIONEX Pennkinetic Extended-Release Suspension 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 TUSSIONEX Pennkinetic Extended-Release Suspension that is written for health professionals.

What are the ingredients in TUSSIONEX Pennkinetic Extended-Release Suspension?

Active Ingredient: hydrocodone polistirex and chlorpheniramine polistirex

Inactive Ingredients: Ascorbic acid, D&C Yellow No. 10, ethylcellulose, FD&C Yellow No. 6, flavor, high fructose corn syrup, methylparaben, polyethylene glycol 3350, polysorbate 80, pregelatinized starch, propylene glycol, propylparaben, purified water, sucrose, vegetable oil, xanthan gum.

Manufactured for: UCB, Inc. Smyrna, GA 30080

For more information about TUSSIONEX Pennkinetic Extended-Release Suspension call 1-844-599-2273 .

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

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