


## DISCLAIMER

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## MEDICATION GUIDE

Promethazine (proe METH a zeen) Hydrochloride and Codeine (KOE deen) Phosphate Syrup, 

### What is the most important information I should know about Promethazine Hydrochloride and Codeine Phosphate Syrup?

- Taking Promethazine Hydrochloride and Codeine Phosphate Syrup with benzodiazepines, or other central nervous system depressants, including alcohol can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.
- Promethazine Hydrochloride and Codeine Phosphate Syrup can cause you to be drowsy. Do not drive a car or operate machinery until you know how Promethazine Hydrochloride and Codeine Phosphate Syrup affects you. Promethazine Hydrochloride and Codeine Phosphate Syrup can slow your thinking and motor skills, and may affect your vision.
- **Do not** give Promethazine Hydrochloride and Codeine Phosphate Syrup to children under 12 years of age or to a child of any age after tonsillectomy or adenoidectomy surgery.
  - When you take Promethazine Hydrochloride and Codeine Phosphate Syrup, 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.
- Avoid giving Promethazine Hydrochloride and Codeine Phosphate Syrup to children between 12 to 18 years of age who have other risk factors for breathing problems. Children with these risk factors may be more sensitive to breathing problems. Children with these risk factors may be more sensitive to breathing problems (respiratory depression) if they take Promethazine Hydrochloride and Codeine Phosphate Syrup:
  - recently had surgery
  - have obstructive sleep apnea
  - are obese
  - have other medical conditions that can cause difficulty breathing, such as neuromuscular problems
  - take other medicines that cause breathing problems
  - have severe lung problems
- You should not breastfeed during treatment with Promethazine Hydrochloride and Codeine Phosphate Syrup.
  - When you take Promethazine Hydrochloride and Codeine Phosphate Syrup, 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 Promethazine Hydrochloride and Codeine Phosphate Syrup, or your breastfeeding baby has any of the symptoms below:
  - increased sleepiness
  - confusion
  - difficulty breathing
  - shallow breathing
  - limpness
  - your baby has difficulty breastfeeding
- Keep Promethazine Hydrochloride and Codeine Phosphate Syrup 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 Promethazine Hydrochloride and Codeine Phosphate Syrup, get emergency medical help right away.
- Promethazine Hydrochloride and Codeine Phosphate Syrup can cause serious side effects including death.
- Take Promethazine Hydrochloride and Codeine Phosphate Syrup exactly as prescribed by your healthcare provider. If you take the wrong dose of Promethazine Hydrochloride and Codeine Phosphate Syrup, you could overdose and die.
- It is especially important when you take Promethazine Hydrochloride and Codeine Phosphate Syrup that you know exactly what dose to take.

### What is Promethazine Hydrochloride and Codeine Phosphate Syrup?

- Promethazine Hydrochloride and Codeine Phosphate Syrup is a prescription medicine used to temporarily treat cough and upper respiratory symptoms that you can have with allergies or a common cold. Promethazine Hydrochloride and Codeine Phosphate Syrup contains 2 medicines, promethazine and codeine. Codeine is a narcotic cough suppressant. Promethazine is an antihistamine.
- **Promethazine Hydrochloride and Codeine Phosphate Syrup is a federal controlled substance (C-V) because it contains codeine that can be abused or lead to dependence.** Keep Promethazine Hydrochloride and Codeine Phosphate Syrup in a safe place to prevent misuse and abuse. Selling or giving away Promethazine Hydrochloride and Codeine Phosphate Syrup may harm others, and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- Promethazine Hydrochloride and Codeine Phosphate Syrup is not for children under 12 years of age.

### Who should not take Promethazine Hydrochloride and Codeine Phosphate Syrup?

- **Do not** give Promethazine Hydrochloride and Codeine Phosphate Syrup to children who are under 12 years of age.
- **Do not** give Promethazine Hydrochloride and Codeine Phosphate Syrup to a child of any age after tonsillectomy or adenoidectomy surgery.
- **Do not** take Promethazine Hydrochloride and Codeine Phosphate Syrup if you are allergic to any of the ingredients in Promethazine Hydrochloride and Codeine Phosphate Syrup. See the end of this Medication Guide for a complete list of ingredients in Promethazine Hydrochloride and Codeine Phosphate Syrup.
- **Do not** take Promethazine Hydrochloride and Codeine Phosphate Syrup if you have asthma.
- **Do not** take Promethazine Hydrochloride and Codeine Phosphate Syrup if you take a medicine called a Monoamine Oxidase Inhibitor (MAOI).

### Before you take Promethazine Hydrochloride and Codeine Phosphate Syrup, tell your healthcare provider about all of your medical conditions, including if you:

- have a drug dependence
- drink alcohol
- have lung or breathing problems including chronic obstructive pulmonary disease (COPD), or sleep apnea
- have kidney or liver problems
- have thyroid problems including hypothyroidism
- have had a head injury
- have pain in your stomach-area (abdomen)
- have Addison's disease
- have a history of severe or persistent cough
- have glaucoma (increased pressure in eyes)
- have prostate problems
- have diabetes
- have problems with your urinary tract (urethral stricture) or difficulty urinating
- have seizures
- have heart problems
- plan to have surgery
- have blood disorders including low white blood cells
- are pregnant or plan to become pregnant. It is not known if Promethazine Hydrochloride and Codeine Phosphate Syrup will harm your unborn baby. You and your healthcare provider should decide if you should take Promethazine Hydrochloride and Codeine Phosphate Syrup while you are pregnant.
- are breastfeeding or plan to breastfeed. Promethazine Hydrochloride and Codeine Phosphate Syrup can pass into your breast milk and may harm your baby. **You should not** breastfeed during treatment with Promethazine Hydrochloride and Codeine Phosphate Syrup.

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

Taking Promethazine Hydrochloride and Codeine Phosphate Syrup with certain other medicines can cause side effects or affect how well Promethazine Hydrochloride and Codeine Phosphate Syrup 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 intestinal problems

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

### How should I take Promethazine Hydrochloride and Codeine Phosphate Syrup?

- Take Promethazine Hydrochloride and Codeine Phosphate Syrup exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much Promethazine Hydrochloride and Codeine Phosphate Syrup to take and when to take it. Do not change your dose without talking to your healthcare provider.
- Ask your pharmacist to give you a measuring device to help you measure the correct amount of Promethazine Hydrochloride and Codeine Phosphate Syrup. Do not use a household teaspoon to measure your medicine. You may accidentally take too much.
- **Do not** take more than 30 mL of Promethazine Hydrochloride and Codeine Phosphate Syrup in 24 hours.
- If you take too much Promethazine Hydrochloride and Codeine Phosphate Syrup, call your healthcare provider or go to the nearest hospital emergency room right away.

### What should I avoid while taking Promethazine Hydrochloride and Codeine Phosphate Syrup?

- Promethazine Hydrochloride and Codeine Phosphate Syrup can cause you to be drowsy. Do not drive a car or use machinery while you take Promethazine Hydrochloride and Codeine Phosphate Syrup until you know how it affects you. Also, watch your child closely when riding a bike.
- **Do not** drink alcohol while taking Promethazine Hydrochloride and Codeine Phosphate Syrup. Drinking alcohol can increase your chances of having serious side effects.
- Avoid spending a long time in sunlight.

### What are the possible side effects of Promethazine Hydrochloride and Codeine Phosphate Syrup?

**Promethazine Hydrochloride and Codeine Phosphate Syrup may cause serious side effects, including:**

- See "What is the most important information I should know about Promethazine Hydrochloride and Codeine Phosphate Syrup?"
- **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 Promethazine Hydrochloride and Codeine Phosphate Syrup exactly as your healthcare provider tells you to take it. Stopping Promethazine Hydrochloride and Codeine Phosphate Syrup suddenly could cause withdrawal symptoms.
- **Bowel problems** including constipation or stomach pain.
- **Feeling dizzy, faint or light-headed, especially when you stand up (orthostatic hypotension).** Light-headedness or fainting may happen when getting up too quickly from a sitting or lying position.

- **Neuroleptic malignant syndrome (NMS) which can lead to death.** Tell your healthcare provider right away if you have any of the following symptoms of NMS:
  - high fever
  - confusion
  - changes in pulse, heart rate, and blood pressure
  - stiff muscles
  - sweating

**The most common side effects of Promethazine Hydrochloride and Codeine Phosphate Syrup include:**

- sleepiness
- nausea and vomiting
- high blood pressure
- confusion
- difficulty urinating
- restlessness
- dryness of mouth, nose, throat
- trouble breathing
- fast heart beat

These are not all the possible side effects of Promethazine Hydrochloride and Codeine Phosphate Syrup.

Call your doctor for medical advice about side effects. You may report side effects to Hi-Tech Pharmacal Co., Inc. at 1-800-262-9010 or FDA at 1-800-FDA-1088.

**How should I store Promethazine Hydrochloride and Codeine Phosphate Syrup?**

- Store Promethazine Hydrochloride and Codeine Phosphate Syrup at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep Promethazine Hydrochloride and Codeine Phosphate Syrup 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 Promethazine Hydrochloride and Codeine Phosphate Syrup and all medicines out of the reach of children.**

**General information about the safe and effective use of Promethazine Hydrochloride and Codeine Phosphate Syrup.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Promethazine Hydrochloride and Codeine Phosphate Syrup for a condition for which it was not prescribed. Do not give Promethazine Hydrochloride and Codeine Phosphate Syrup 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 Promethazine Hydrochloride and Codeine Phosphate Syrup that is written for health professionals.

**What are the ingredients in Promethazine Hydrochloride and Codeine Phosphate Syrup?**

**Active ingredients:** promethazine hydrochloride and codeine phosphate

**Inactive ingredients:** Alcohol 7%, artificial boysenberry flavor, ascorbic acid, citric acid, D&C Red No. 33, FD&C Blue No. 1, FD&C Yellow No. 6, methylparaben, propylene glycol, propylparaben, purified water, saccharin sodium, sodium benzoate, sodium citrate, and sucrose syrup.

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

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