

## **MEDICATION GUIDE**

Promethazine (proe METH a zeen) with Codeine (KOE deen) Oral Solution, C-V  
(Promethazine Hydrochloride and Codeine Phosphate Oral Solution)

### **What is the most important information I should know about Promethazine with Codeine Oral Solution?**

- Taking Promethazine with Codeine Oral Solution with benzodiazepines, or other central nervous system depressants, including alcohol can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.
- Promethazine with Codeine Oral Solution can cause you to be drowsy. Do not drive a car or operate machinery until you know how Promethazine with Codeine Oral Solution affects you. Promethazine with Codeine Oral Solution can slow your thinking and motor skills, and may affect your vision.
- **Do not** give Promethazine with Codeine Oral Solution to children under 12 years of age **or** to a child younger than 18 years of age after tonsillectomy or adenoidectomy surgery.
  - When you take Promethazine with Codeine Oral Solution, 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 with Codeine Oral Solution 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 (respiratory depression) if they take Promethazine with Codeine Oral Solution:
  - 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 with Codeine Oral Solution.
  - When you take Promethazine with Codeine Oral Solution, 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 with Codeine Oral Solution, or your breastfeeding baby has any of the symptoms below:
  - increased sleepiness
  - shallow breathing
  - confusion
  - limpness
  - difficulty breathing
  - your baby has difficulty breastfeeding
- Keep Promethazine with Codeine Oral Solution 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 with Codeine Oral Solution, get emergency medical help right away.
- Promethazine with Codeine Oral Solution can cause serious side effects including death.

- Take Promethazine with Codeine Oral Solution exactly as prescribed by your healthcare provider. If you take the wrong dose of Promethazine with Codeine Oral Solution, you could overdose and die.
- It is especially important when you take Promethazine with Codeine Oral Solution that you know exactly what dose to take.

#### **What is Promethazine with Codeine Oral Solution?**

- Promethazine with Codeine Oral Solution is a prescription medicine used to temporarily treat cough and upper respiratory symptoms that you can have with allergies or a common cold. Promethazine with Codeine Oral Solution contains 2 medicines, promethazine and codeine. Codeine is a narcotic cough suppressant. Promethazine is an antihistamine.
- **Promethazine with Codeine Oral Solution is a federal controlled substance (C-V) because it contains codeine that can be abused or lead to dependence.** Keep Promethazine with Codeine Oral Solution in a safe place to prevent misuse and abuse. Selling or giving away Promethazine with Codeine Oral Solution 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 with Codeine Oral Solution is not for children under 12 years of age.

#### **Who should not take Promethazine with Codeine Oral Solution?**

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

#### **Before you take Promethazine with Codeine Oral Solution, 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 Addison's disease
- have pain in your stomach-area (abdomen)
- have glaucoma (increased pressure in eyes)
- have a history of severe or persistent cough
- have diabetes
- have prostate problems
- have seizures
- have problems with your urinary tract (urethral stricture) or difficulty urinating
- have heart problems
- have blood disorders including low white blood cells
- plan to have surgery

- are pregnant or plan to become pregnant. It is not known if Promethazine with Codeine Oral Solution will harm your unborn baby. You and your healthcare provider should decide if you should take Promethazine with Codeine Oral Solution while you are pregnant.
- are breastfeeding or plan to breastfeed. Promethazine with Codeine Oral Solution can pass into your breast milk and may harm your baby. **You should not** breastfeed during treatment with Promethazine with Codeine Oral Solution.

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

Taking Promethazine with Codeine Oral Solution with certain other medicines can cause side effects or affect how well Promethazine with Codeine Oral Solution 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 with Codeine Oral Solution?**

- Take Promethazine with Codeine Oral Solution exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much Promethazine with Codeine Oral Solution 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 with Codeine Oral Solution. 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 with Codeine Oral Solution in 24 hours.
- If you take too much Promethazine with Codeine Oral Solution, call your healthcare provider or go to the nearest hospital emergency room right away.

#### **What should I avoid while taking Promethazine with Codeine Oral Solution?**

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

#### **What are the possible side effects of Promethazine with Codeine Oral Solution?**

**Promethazine with Codeine Oral Solution may cause serious side effects, including:**

- See “**What is the most important information I should know about Promethazine with Codeine Oral Solution?**”
- **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 with Codeine Oral Solution exactly as your healthcare provider tells you to take it. Stopping Promethazine with Codeine Oral Solution 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
  - stiff muscles
  - sweating
  - changes in pulse, heart rate, and blood pressure

**The most common side effects of Promethazine with Codeine Oral Solution 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 with Codeine Oral Solution. 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 Promethazine with Codeine Oral Solution?**

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

**General information about the safe and effective use of Promethazine with Codeine Oral Solution.**

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

**What are the ingredients in Promethazine with Codeine Oral Solution?**

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

**Inactive ingredients:** Ascorbic acid, citric acid, FD&C blue #1, FD&C red #3, grape blend flavor, menthol, methylparaben, propylene glycol, propylparaben, purified water, saccharin sodium, sodium benzoate, sodium citrate and sucrose.

Distributed by: **Par Pharmaceutical, Chestnut Ridge, NY 10977**

For more information, call 1-800-828-9393.

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

Issued: 07/2017  
R4