

MEDICATION GUIDE

Promethazine (proe METH a zeen) with Codeine (KOE deen) Oral Solution, CV

(Promethazine Hydrochloride and Codeine Phosphate Oral Solution)

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

- Promethazine Hydrochloride and Codeine Phosphate Oral Solution can cause children to stop breathing (respiratory depression) and cause death.
 - Do not give Promethazine Hydrochloride and Codeine Phosphate Oral Solution 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 Promethazine Hydrochloride and Codeine Phosphate Oral Solution 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 Promethazine Hydrochloride and Codeine Phosphate Oral Solution 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 Promethazine Hydrochloride and Codeine Phosphate Oral Solution 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 Promethazine Hydrochloride and Codeine Phosphate Oral Solution. Ask your healthcare provider for a list of these medicines if you are not sure.
- Promethazine Hydrochloride and Codeine Phosphate Oral Solution can cause breathing problems (respiratory depression) and drowsiness.
 - Take Promethazine Hydrochloride and Codeine Phosphate Oral Solution exactly as prescribed by your healthcare provider. If you take the wrong dose of Promethazine Hydrochloride and Codeine Phosphate Oral Solution you could overdose and die. See the Medication Guide section called "How should I take Promethazine Hydrochloride and Codeine Phosphate Oral Solution?" for important information about how to take Promethazine Hydrochloride and Codeine Phosphate Oral Solution correctly.
 - Avoid driving a car or operating machinery during treatment with Promethazine Hydrochloride and Codeine Phosphate Oral Solution.
- Call your healthcare provider or get emergency medical help right away if anyone taking Promethazine Hydrochloride and Codeine Phosphate Oral Solution, 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 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 Hydrochloride and Codeine Phosphate Oral Solution, get emergency medical help right away.

What is Promethazine Hydrochloride and Codeine Phosphate Oral Solution?

- Promethazine Hydrochloride and Codeine Phosphate Oral Solution is a prescription medicine used to temporarily treat cough and upper respiratory symptoms, including a stuffy nose (nasal congestion) that you can have with allergies or a common cold. Promethazine Hydrochloride and Codeine Phosphate Oral Solution contains 2 medicines, promethazine and codeine. Promethazine is an antihistamine. Codeine is a narcotic cough suppressant.
- **Promethazine Hydrochloride and Codeine Phosphate Oral Solution 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 Oral Solution in a safe place to prevent misuse and abuse. Selling or giving away Promethazine Hydrochloride and Codeine Phosphate 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 Hydrochloride and Codeine Phosphate Oral Solution is not for children under 12 years of age.

Who should not take Promethazine Hydrochloride and Codeine Phosphate Oral Solution?

- **Do not** give Promethazine Hydrochloride and Codeine Phosphate Oral Solution to children younger than 12 years of age.
- **Do not** give Promethazine Hydrochloride and Codeine Phosphate Oral Solution to children younger than 18 years of any age after tonsillectomy or adenoidectomy surgery.
- **Do not** take Promethazine Hydrochloride and Codeine Phosphate Oral Solution if you are allergic to any of the ingredients in Promethazine Hydrochloride and Codeine Phosphate Oral Solution. See the end of this Medication Guide for a complete list of ingredients in Promethazine Hydrochloride and Codeine Phosphate Oral Solution.
- **Do not** take Promethazine Hydrochloride and Codeine Phosphate Oral Solution if you have asthma.
- **Do not** take Promethazine Hydrochloride and Codeine Phosphate Oral Solution if you have high blood pressure or narrowing of blood vessels to your legs or arms (peripheral vascular insufficiency).
- **Do not** take Promethazine Hydrochloride and Codeine Phosphate Oral Solution if you take a medicine called a Monoamine Oxidase Inhibitor (MAOI).

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

- have a drug dependence
- have lung or breathing problems including chronic obstructive pulmonary disease (COPD), or sleep apnea.
- have had a head injury
- have pain in your stomach-area (abdomen)
- have a history of severe or persistent cough
- have prostate problems
- have problems with your urinary tract (urethral stricture) or difficulty urinating
- have had surgery recently or plan to have surgery
- drink alcohol
- have kidney or liver problems
- have thyroid problems including hypothyroidism
- have Addison's disease
- have glaucoma (increased pressure in eyes)
- have diabetes
- have seizures

- have heart problems or blood vessel (cardiovascular) problems including high blood pressure or peripheral vascular insufficiency See "**Who should not take Promethazine Hydrochloride and Codeine Phosphate Oral Solution?**"
- 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 Oral Solution will harm your unborn baby. You and your healthcare provider should decide if you should take Promethazine Hydrochloride and Codeine Phosphate Oral Solution while you are pregnant.
- are breastfeeding or plan to breastfeed. Codeine Phosphate passes into your breast milk and may harm your baby. It is not known if Promethazine Hydrochloride can pass into your breast milk. You should not breastfeed during treatment with Promethazine Hydrochloride and Codeine Phosphate 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 Hydrochloride and Codeine Phosphate Oral Solution with certain other medicines can cause side effects or affect how well Promethazine Hydrochloride and Codeine Phosphate 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) or tricyclic antidepressants (TCAs)
- take medicines for stomach or intestinal problems
- take ergot containing medicines
- take medicines called alpha blockers
- take medicines called beta blockers
- take stimulants or uppers (amphetamines)

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 Oral Solution?

- Take Promethazine Hydrochloride and Codeine Phosphate Oral Solution exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much Promethazine Hydrochloride and Codeine Phosphate 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 Hydrochloride and Codeine Phosphate 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 Hydrochloride and Codeine Phosphate Oral Solution in 24 hours.
- If you take too much Promethazine Hydrochloride and Codeine Phosphate Oral Solution, 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 Oral Solution?

- Promethazine Hydrochloride and Codeine Phosphate Oral Solution can cause you to be drowsy. Avoid driving a car or operating machinery during the treatment with Promethazine Hydrochloride and Codeine Phosphate Oral Solution. Also, watch your child closely when riding a bike.

- Avoid drinking alcohol during the treatment with Promethazine Hydrochloride and Codeine Phosphate Oral Solution. 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 Oral Solution? Promethazine Hydrochloride and Codeine Phosphate Oral Solution may cause serious side effects, including:

- See "What is the most important information I should know about Promethazine Hydrochloride and Codeine Phosphate 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 Hydrochloride and Codeine Phosphate Oral Solution exactly as your healthcare provider tells you to take it. Stopping Promethazine Hydrochloride and Codeine Phosphate Oral Solution suddenly could cause withdrawal symptoms.
- **Bowel problems** including constipation or stomach pain.
- Increased intracranial pressure.
- **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 you healthcare provider right away if you have any of the following symptoms of NMS:
 - high fever
 - stiff muscles
 - confusion
 - sweating
 - changes in pulse, heart rate, and blood pressure

The most common side effects of Promethazine Hydrochloride and Codeine Phosphate Oral Solution include:

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

These are not all the possible side effects of Promethazine Hydrochloride and Codeine Phosphate 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 Hydrochloride and Codeine Phosphate Oral Solution?

- Store Promethazine Hydrochloride and Codeine Phosphate Oral Solution at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep Promethazine Hydrochloride and Codeine Phosphate 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 Hydrochloride and Codeine Phosphate Oral Solution and all medicines**

out of the reach of children.

General information about the safe and effective use of Promethazine Hydrochloride and Codeine Phosphate Oral Solution.

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

What are the ingredients in Promethazine Hydrochloride and Codeine Phosphate Oral Solution?

Active ingredients: promethazine hydrochloride and codeine phosphate

Inactive ingredients: Artificial raspberry flavor, ascorbic acid, citric acid anhydrous, D&C Red #33, dehydrated alcohol, edetate disodium, FD&C Blue #1, glycerin, liquid sugar, methylparaben, purified water, saccharin sodium, sodium benzoate, sodium citrate dihydrate and sodium propionate.

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For more information, go to www.wockhardtusa.com or call Wockhardt USA, LLC at 1-800-346-6854.

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