

MEDICATION GUIDE

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

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

Promethazine Hydrochloride and Codeine Phosphate Oral Solution is not for children under 18 years of age.

Promethazine Hydrochloride and Codeine Phosphate Oral Solution can cause serious side effects, including:

- **Addiction, abuse and misuse.** Taking Promethazine Hydrochloride and Codeine Phosphate Oral Solution or other medicines that contain an opioid can cause addiction, abuse, and misuse, which can lead to overdose and death. This can happen even if you take Promethazine Hydrochloride and Codeine Phosphate Oral Solution exactly as prescribed by your healthcare provider. Your risk of addiction, abuse, and misuse is increased if you or a family member has a history of drug or alcohol abuse or addiction, or mental health problems.
 - **Do not** share your Promethazine Hydrochloride and Codeine Phosphate Oral Solution with other people.
 - Keep Promethazine Hydrochloride and Codeine Phosphate Oral Solution in a safe place away from children.
- **Life-threatening breathing problems (respiratory depression).** Promethazine Hydrochloride and Codeine Phosphate Oral Solution can cause breathing problems (respiratory depression) that can happen at any time during treatment and can lead to death. Your risk of breathing problems is greatest when you first start taking Promethazine Hydrochloride and Codeine Phosphate Oral Solution, are taking other medicines that can cause breathing problems, have certain lung problems, are elderly or have certain other health problems. **Children are at higher risk for respiratory depression.** Breathing problems can happen even if you take Promethazine Hydrochloride and Codeine Phosphate Oral Solution exactly as prescribed by your healthcare provider.
- 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
- **Keep Promethazine Hydrochloride and Codeine Phosphate Oral Solution in a safe**
 - **place away from children.** Accidental use of even 1 dose of Promethazine Hydrochloride and Codeine Phosphate Oral Solution, especially by a child, is a medical emergency and can cause breathing problems (respiratory depression) which can lead to death. If a child accidentally takes Promethazine Hydrochloride and Codeine Phosphate Oral Solution, get emergency medical help right away.
 - **Overdose and death due to medicine dosing errors.** Over dose and death can happen if you measure the wrong dose of Promethazine Hydrochloride and Codeine Phosphate Oral Solution. Always use an accurate milliliter (mL) measuring device to 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. You can ask your pharmacist for the measuring device you should use and how to measure the correct dose.
 - **Breathing problems (respiratory depression)** that can lead to death and opioid withdrawal can happen if you start taking or stop taking other medicines while taking Promethazine Hydrochloride and Codeine Phosphate Oral Solution, including:

- certain antibiotics
- certain medicines to treat a fungal infection
- certain medicines to treat Human Immunodeficiency Virus (HIV)-1 infection, Acquired Immune Deficiency Syndrome (AIDS), or Hepatitis C
- rifampin
- carbamazepine
- phenytoin
- **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.
- **Do not** take any benzodiazepines or medicines that can cause drowsiness or sleepiness 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.
- **Do not** drink alcohol during treatment with Promethazine Hydrochloride and Codeine Phosphate Oral Solution.
- **Opioid withdrawal in a newborn.** Use of Promethazine Hydrochloride and Codeine Phosphate Oral Solution during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated. You should not take Promethazine Hydrochloride and Codeine Phosphate Oral Solution if you are pregnant. Tell your healthcare provider right away if you are pregnant or think you may be pregnant.

What is Promethazine Hydrochloride and Codeine Phosphate Oral Solution?

- Promethazine Hydrochloride and Codeine Phosphate Oral Solution is a prescription medicine used in adults to temporarily treat cough and upper respiratory symptoms 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 an opioid (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.

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 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.

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

Promethazine Hydrochloride and Codeine Phosphate Oral Solution is not for children under 18 years of age. See “What is the most important information I should know about Promethazine Hydrochloride and Codeine Phosphate Oral Solution?”

Do not take Promethazine Hydrochloride and Codeine Phosphate Oral Solution if you:

- have severe breathing problems (respiratory depression). See **“What is the most important information I should know about Promethazine Hydrochloride and Codeine Phosphate Oral Solution?”**
 - have a blockage (obstruction) in your bowel such as a paralytic ileus.
 - take a medicine called a monoamine oxidase inhibitor (MAOI).
 - **Do not** take an MAOI within 14 days after you stop taking Promethazine Hydrochloride and Codeine Phosphate Oral Solution.
 - **Do not** start taking Promethazine Hydrochloride and Codeine Phosphate Oral Solution if you stopped taking an MAOI in the last 14 days.
 - have a type of glaucoma called “narrow angle glaucoma”.
 - have problems with your urinary tract or difficulty urinating (urinary retention).
 - are allergic to promethazine, codeine, or 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. You may have an increased risk of an allergic reaction to Promethazine Hydrochloride and Codeine Phosphate Oral Solution if you are allergic to certain other opioid medicines.
- Ask your healthcare provider if you have any questions about this information.**

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 addiction
- have lung or breathing problems
- have a fever and are coughing up mucus
- have had a recent head injury
- have had brain tumor or other brain problems
- have or have had seizures
- have pain in your stomach-area (abdomen)
- have constipation or other bowel problems
- have bile duct or pancreas problems
- have kidney or liver problems
- have prostate problems
- plan to have surgery
- have problems with your urinary tract or difficulty urinating
- have uncontrolled spasms of your face, neck or muscles of your body, arms and legs (dystonia)
- have a history of neuroleptic malignant syndrome (NMS)
- have blood disorders including low white blood cells
- have low blood pressure (hypotension)
- have adrenal gland problems
- are pregnant or plan to become pregnant. Promethazine Hydrochloride and Codeine Phosphate Oral Solution can harm your unborn baby. See **“What is the most important information I should know about Promethazine Hydrochloride and Codeine Phosphate Oral Solution?”**
- are breastfeeding or plan to breastfeed. Codeine Phosphate passes into your breast milk and can cause serious side effects in your baby including increased sleepiness, breathing problems (respiratory depression), and death. It is not known if Promethazine Hydrochloride can pass into your breast milk. You and your healthcare provider should decide if you will take Promethazine Hydrochloride and Codeine Phosphate Oral Solution or breastfeed. You should not do both. See **“What should I avoid while taking Promethazine Hydrochloride and Codeine Phosphate Oral Solution?”**

- plan to have children. Promethazine Hydrochloride and Codeine Phosphate Oral Solution may affect the ability to have a child in females and males (fertility problems). It is not known if these fertility problems will be reversible, even after you stop taking 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:

- See **“What is the most important information I should know about Promethazine Hydrochloride and Codeine Phosphate Oral Solution?”**
- take pain medicines such as opioids (narcotics).
- take cold or allergy medicines that contain antihistamines or cough suppressants.
- drink alcohol.
- take muscle relaxants.
- take certain medicines used to treat mood, anxiety, psychotic or thought disorders, or depression, including monoamine oxidase inhibitors (MAOIs), tricyclics, selective serotonin reuptake inhibitors (SSRIs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), or antipsychotics.
- take water pills (diuretics).
- take medicines called “anticholinergics” used to treat asthma, chronic bronchitis (COPD), or stomach 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 Oral Solution?

- See **“What is the most important information I should know about 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. Do not change your dose without talking to your healthcare provider.
- Take Promethazine Hydrochloride and Codeine Phosphate Oral Solution by mouth only.
- **Do not** take more than 30 mL of Promethazine Hydrochloride and Codeine Phosphate Oral Solution in 24 hours.
- Take Promethazine Hydrochloride and Codeine Phosphate Oral Solution using an accurate millimeter (mL) measuring device. If you do not have one, ask your pharmacist to give you a measuring device to 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 overfill the measuring device.
- Rinse your measuring device with water after each use.
- 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.
- Tell your healthcare provider if your cough does not get better within 5 days of treatment with Promethazine Hydrochloride and Codeine Phosphate Oral Solution.

What should I avoid while taking Promethazine Hydrochloride and Codeine Phosphate Oral Solution?

- Avoid driving a car or operating machinery during treatment with Promethazine Hydrochloride and Codeine Phosphate Oral Solution. Promethazine Hydrochloride and Codeine Phosphate Oral Solution can cause you to be drowsy, slow your thinking and motor skills, and affect your vision.
- **Do not** drink alcohol during treatment with Promethazine Hydrochloride and Codeine Phosphate Oral Solution. Drinking alcohol with Promethazine Hydrochloride and Codeine Phosphate Oral Solution can increase your chances of having serious side effects, accidental overdose, and cause death.

Avoid the use of Promethazine Hydrochloride and Codeine Phosphate Oral Solution if you:

- are pregnant. Use of Promethazine Hydrochloride and Codeine Phosphate Oral Solution during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated. Tell your healthcare provider right away if you are pregnant or think you may be pregnant.
- are breastfeeding. Use of Promethazine Hydrochloride and Codeine Phosphate Oral Solution while breastfeeding can cause severe breathing problems (respiratory depression) that could be life-threatening.

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?”**
- **Bowel problems including constipation or stomach pain.** See **“Who should not take Promethazine Hydrochloride and Codeine Phosphate Oral Solution?”**
- **Increased pressure in your head (increased intracranial pressure).** Avoid the use of Promethazine Hydrochloride and Codeine Phosphate Oral Solution if you have a head injury or have been told that you have changes in the tissue of your brain (brain lesions) or increased pressure in your head.
- **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
 - stiff muscles
 - confusion
 - sweating
 - changes in pulse, heart rate, or blood pressure
- **Uncontrolled spasms of your face and neck muscles, or muscles of your body, arms, and legs (dystonia).** These muscle spasms can cause abnormal movements and body positions, and speech problems. These spasms may happen after one dose of Promethazine Hydrochloride and Codeine Phosphate Oral Solution. Tell your healthcare provider if you have any of these symptoms.
- **Increased risk of seizures in people with seizure disorders.** If you have a seizure disorder, Promethazine Hydrochloride and Codeine Phosphate Oral Solution may increase how often you have seizures.
- **Low blood pressure.** A sudden drop in blood pressure can happen in some people during treatment with Promethazine Hydrochloride and Codeine Phosphate Oral Solution and this may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up (orthostatic hypotension). Your risk of having this problem may be increased if you take Promethazine Hydrochloride and Codeine Phosphate Oral Solution with certain other medicines that lower blood pressure. If you have any of these symptoms while taking Promethazine Hydrochloride and Codeine Phosphate Oral Solution, sit or lie down. Do not change your body position too fast. Get up slowly from sitting or lying down.
- **Adrenal gland problems.** Promethazine Hydrochloride and Codeine Phosphate Oral Solution can cause serious and life-threatening adrenal gland problems. Your healthcare provider may do blood tests to check for adrenal gland problems. Call your healthcare provider right away if you have any of these symptoms:
 - nausea
 - vomiting
 - not wanting to eat
 - fatigue
 - weakness
 - dizziness
 - low blood pressure
- **Changes in laboratory blood levels,** including high blood sugar and false pregnancy test reading.

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

- sleepiness
- confusion
- coordination problems
- decrease in mental and physical performance
- lack of energy
- lightheadedness
- dizziness
- headache
- dry mouth

- irritability
- anxiety
- restlessness
- nervousness
- tremor

- difficulty urinating
- sweating
- shortness of breath
- nausea
- vomiting
- constipation

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).
- Store Promethazine Hydrochloride and Codeine Phosphate Oral Solution in a tightly closed container, in a dry, cool place away from heat or direct sunlight.
- **Keep Promethazine Hydrochloride and Codeine Phosphate Oral Solution and all medicines out of the reach of children.**

How should I dispose of Promethazine Hydrochloride and Codeine Phosphate Oral Solution?

Remove unused Promethazine Hydrochloride and Codeine Phosphate Oral Solution from the container and mix it with an undesirable, non-toxic substance such as cat litter or used coffee grounds to make it less appealing to children and pets. Place the mixture in a container such as a sealed plastic bag and throw it away in the household trash. You can also follow your state or local guidelines on how to safely throw away Promethazine Hydrochloride and Codeine Phosphate Oral Solution.

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: anhydrous citric acid, ascorbic acid, D&C Red # 33, edetate disodium, FD&C Blue #1, methylparaben, peach-mint flavor, propylene glycol, propylparaben, purified water, saccharin sodium, sodium benzoate, sodium citrate anhydrous, sodium metabisulfite, sucrose.

Manufactured by:

Tris Pharma, Inc.

Monmouth Junction, NJ 08852

For more information, go to www.trispharma.com or call 1-732-940-0358.

LB8082

Rev. 07 03/2018

This Medication Guide has been approved by the U.S. Food and Drug Administration. Approved: March 2018