

PROMETHAZINE AND CODEINE

Pronunciation: KOE deen and proe METH a zeen

Brand: Codeine Phosphate-Promethazine HCl, Promethazine with Codeine

What is the most important information I should know about codeine and promethazine?

- **MISUSE OF OPIOID MEDICINE CAN CAUSE ADDICTION, OVERDOSE, OR DEATH.** Keep the medication in a place where others cannot get to it.
- **Taking opioid medicine during pregnancy may cause life-threatening withdrawal symptoms in the newborn.**
- **Fatal side effects can occur if you use opioid medicine with alcohol, or with other drugs that cause drowsiness or slow your breathing.**

What is codeine and promethazine?

- Codeine and promethazine is a combination medicine used to treat cold or allergy symptoms such as runny nose, sneezing, and cough.
- Codeine and promethazine contains an opioid (narcotic) cough medicine, and may be habit-forming.
- Codeine and promethazine may also be used for purposes not listed in this medication guide.

What should I discuss with my healthcare provider before taking codeine and promethazine?

- You should not use this medicine if you are allergic to codeine or promethazine, or if you have:
 - asthma or severe breathing problems;
 - a stomach or bowel obstruction (including paralytic ileus);
 - narrow-angle glaucoma; or
 - if you are unable to urinate.
- **Do not use this medicine if you have used an MAO inhibitor in the past 14 days.** A dangerous drug interaction could occur. MAO inhibitors include isocarboxazid, linezolid, methylene blue injection, phenelzine, rasagiline, selegiline, tranylcypromine, and others.
- Codeine and promethazine is **not approved** for use by anyone younger than 12 years old.
- **Do not** give this medicine to anyone younger than 18 years old who recently had surgery to remove the tonsils or adenoids.
- Tell your doctor if you have ever had:
 - lung disease or breathing problems;
 - a head injury, brain tumor, or seizure;
 - constipation, a bowel obstruction, or stomach problems;
 - problems with your bile duct, pancreas, or adrenal gland;
 - an enlarged prostate or urination problems;
 - uncontrolled muscle spasms;
 - a blood cell disorder;
 - neuroleptic malignant syndrome (a severe nervous system reaction);
 - liver or kidney disease;
 - low blood pressure;
 - a drug addiction; or
 - if you have a fever and cough with mucus.
- **If you use opioid medicine while you are pregnant, your baby could become dependent on the drug.**
- This can cause life-threatening withdrawal symptoms in the baby after it is born. Babies born dependent on opioids may need medical treatment for several weeks.
- **Do not breast-feed.** Codeine can pass into breast milk and may cause drowsiness, breathing problems, or death in a nursing baby.

How should take codeine and promethazine?

- Follow the directions on your prescription label and read all medication guides. **Never use this medicine in larger amounts, or for longer than prescribed.** Take this medicine only until your symptoms clear up.
- **Never share opioid medicine with another person, especially someone with a history of drug abuse or addiction. MISUSE CAN CAUSE ADDICTION, OVERDOSE, OR DEATH.** Keep the medication in a place where others cannot get to it. Selling or giving away opioid medicine is against the law.
- Measure **liquid medicine** carefully. Use the dosing syringe provided, or use a medicine dose-measuring device (not a kitchen spoon). Rinse after each use.
- Call your doctor if your symptoms do not improve after 5 days of treatment.
- If you need surgery or medical tests, tell the surgeon or doctor ahead of time if you have taken a cough or cold medicine within the past few days.
- Store at room temperature away from moisture, heat, and light. Keep track of your medicine. You should be aware if anyone is using your medicine improperly or without a prescription.
- Do not keep leftover medication. **Just one dose can cause death in someone using this medicine accidentally or improperly.** Read and carefully follow the instructions provided with this medicine about how to safely dispose of any unused portion.

What happens if I miss a dose?

- Since this medicine is used when needed, you may not be on a dosing schedule. Skip any missed dose if it's almost time for your next dose. **Do not** use two doses at one time.

What happens if I overdose?

- Seek emergency medical attention or call the Poison Help line at 1-800-222-1222. **A codeine overdose can be fatal, especially in a child or other person using the medicine without a prescription.**
- Overdose symptoms may include slow breathing and heart rate, severe drowsiness, muscle weakness, cold and clammy skin, pinpoint pupils, and fainting.

What should I avoid while taking codeine and promethazine?

- Avoid driving or operating machinery until you know how this medicine will affect you. Dizziness or severe drowsiness can cause falls or other accidents.
- **Do not drink alcohol.** Dangerous side effects or death could occur.

What are the possible side effects of codeine and promethazine?

- Get emergency medical help if you have **signs of an allergic reaction:** hives; difficult breathing; swelling of your face, lips, tongue, or throat.
- **Opioid medicine can slow or stop your breathing, and death may occur.** A person caring for you should seek emergency medical attention if you have slow breathing with long pauses, blue colored lips, or if you are hard to wake up.
- Stop using this medicine and call your doctor at once if you have:
 - noisy breathing, sighing, shallow breathing;
 - extreme drowsiness, confusion, feeling weak or limp;
 - uncontrolled muscle movements in your face, neck, arms, or legs;
 - a light-headed feeling, like you might pass out;
 - a seizure;
 - **adrenal gland problems** --nausea, vomiting, loss of appetite, dizziness, worsening tiredness or weakness; or
 - **severe nervous system reaction** --very stiff (rigid) muscles, high fever, sweating, confusion, fast or uneven heartbeats, tremors.
- **Seek medical attention right away if you have symptoms of serotonin syndrome, such as:** agitation, hallucinations, fever, sweating, shivering, fast heart rate, muscle stiffness, twitching, loss of coordination, nausea, vomiting, or diarrhea.
- Common side effects may include:
 - dry mouth, nausea, vomiting, constipation;
 - confusion, dizziness, headache;
 - drowsiness, lack of energy;
 - tremors, coordination problems;
 - feeling anxious, restless, nervous, or irritable;
 - urination problems;
 - sweating; or
 - shortness of breath.
- This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What other drugs will affect codeine and promethazine?

- **You may have breathing problems or withdrawal symptoms if you start or stop taking certain other medicines.** Tell your doctor if you also use an antibiotic, antifungal medication, heart or blood pressure medication, seizure medication, or medicine to treat HIV or hepatitis C.
- **Opioid medication can interact with many other drugs and cause dangerous side effects or death.**
- Be sure your doctor knows if you also use:
 - cold or allergy medicines, bronchodilator asthma/COPD medication, or a diuretic ("water pill");
 - medicines for motion sickness, irritable bowel syndrome, or overactive bladder;
 - **other narcotic medications** --opioid pain medicine or prescription cough medicine;
 - **a sedative like Valium** --diazepam, alprazolam, lorazepam, Xanax, Klonopin, Versed, and others;
 - **drugs that make you sleepy or slow your breathing** --a sleeping pill, muscle relaxer, medicine to treat mood disorders or mental illness; or
 - **drugs that affect serotonin levels in your body** --a stimulant, or medicine for depression, Parkinson's disease, migraine headaches, serious infections, or nausea and vomiting.
- This list is not complete. Other drugs may affect codeine and promethazine, including prescription and over the counter medicines, vitamins, and herbal products. **Not all possible interactions are listed here.**

Where can I get more information?

- Your healthcare provider or pharmacist can provide more information about codeine and promethazine.

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use this medication only for the indication prescribed.