



Patient Information Sheet

Promethazine HCl (marketed as Phenergan and generic products)

This is a summary of the most important information about promethazine. For details, talk to your healthcare professional.

FDA ALERT [04/2006] Medications containing promethazine hydrochloride (HCl) should not be used for children less than two years old because of possible breathing problems. This includes promethazine HCl in any form: syrups, suppositories, tablets, or injectables. Cases of breathing problems, some causing death, have been reported to the FDA when the drug was used in children less than two years old. Parents and caregivers should also be careful and get a doctor's advice about giving promethazine HCl in any form to children age two and older. The labeling on all products, brand name and generic, has been changed to reflect these strengthened warnings. One manufacturer of suppositories and tablets has notified healthcare professionals of the changed label. The FDA is issuing this safety alert to make sure that healthcare professionals, other caregivers, and patients realize that the warnings apply to promethazine HCl syrups as well.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA intends to update this sheet when additional information or analyses become available

FDA approved labeling for promethazine contains a serious warning about the risk of serious breathing problems when promethazine is used by children.

What Is Promethazine?

Promethazine is an antihistamine which can be taken by mouth as a tablet or syrup, rectally as a suppository, or by injection. It can be used for:

- "hay fever," or, a stuffy runny nose from allergy
- watery, itchy eyes due to inhaled allergies and foods
- mild allergic skin reactions with itching and swelling
- allergic reactions to blood or plasma
- dermatographism, a form of hives known as "skin writing"
- serious allergic reactions along with epinephrine and other treatments
- sedation before or after surgery, or during childbirth
- prevention and control of nausea and vomiting after surgery
- along with meperidine (demerol) or other pain medicines
- sedation, relief of anxiety, and production of light sleep from which the patient can be easily aroused
- treatment and prevention of motion sickness

Who Should Not Use Promethazine?

Promethazine should not be given to:

- children under two years of age
- patients who are unconscious
- patients who are allergic to promethazine, any of the ingredients in promethazine, or to other phenothiazines
- patients with lung symptoms including asthma
- children who are vomiting unless the vomiting is prolonged and there is a known cause

What Are The Risks?

The following are the major potential risks and side effects of promethazine therapy. However, this list is not complete.

- **Severe drowsiness and reduced mental alertness.** Promethazine may cause drowsiness which may impair your ability to ride a bike, drive a car, or operate machinery. This may be worsened if taken with alcohol or other drugs that also cause central nervous system (CNS) slowing such as sedatives, pain medicines, tranquilizers or certain drugs for depression.
- **Serious breathing problems.** Promethazine should not be used in patients with poor lung function such as chronic obstructive lung disease or breathing problems while sleeping (sleep apnea).
- **Increased risk of seizures.** Promethazine should be used with caution in patients with seizures or who are on other medicines which may also increase the risk of seizures.
- **Bone-marrow problems and blood cell production.** Promethazine should not be used in patients with bone-marrow problems or used with other drugs that affect the bone marrow's production of blood cells.
- **Neuroleptic malignant syndrome.** This potentially deadly syndrome includes symptoms such as fever, muscle rigidity, mental changes, changes in pulse or blood pressure, fast heartbeat, increased sweating or irregular heart rhythm.
- **The most common side effects are** drowsiness, changes in blood pressure, skin reactions, blood cell changes and breathing problems. Increased excitability or abnormal movements may occur after one dose of promethazine. If they do, consult your doctor about using another medicine.

What Should I Tell My Healthcare Professional?

Before you start taking promethazine, tell your healthcare professional if you:

- have narrow-angle glaucoma
- have an enlarged prostate
- have a stomach ulcer





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- have an intestinal blockage
- have a bladder blockage
- have heart problems
- have liver problems
- have breathing or lung problems
- have sleep apnea (breathing problems when sleeping)
- have seizures
- drink alcohol
- are trying to become pregnant, are already pregnant, or are breast-feeding

Can Other Medicines Or Food Affect Promethazine?

Promethazine and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how promethazine works or

promethazine may affect how your other medicines work. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

Especially tell your healthcare professional if you take:

- medicines that affect your brain such as anti-anxiety medicine, sleeping pills, pain medicines, sedatives, narcotics, antidepressants or tranquilizers
- epinephrine
- a monoamine oxidase inhibitor (MAOI) which is used to treat depression or other mental disorders
- medicines called anticholinergics

Date this drug was approved: 3/1951

