

Safety Alert

July 2024

Promethazine—Contraindication in children under 6 years of age due to the risk of psychiatric and central nervous system side effects .

EDA performs label update to include the following:

DOSE AND METHOD OF ADMINISTRATION

Dose

This product should not be used in children under 6 years of age

4.3 CONTRAINDICATIONS

Promethazine is contraindicated for use in:

- Newborns or premature infants
- **Children less than 6 years of age**

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Paediatric Use

Children may experience paradoxical excitation with promethazine. The use of promethazine should be avoided in children and adolescents with signs and symptoms suggestive of Reye's Syndrome. **This product must not be used in children under 6 years of age, due to the potential for fatal respiratory depression, psychiatric and CNS events.** Caution should be exercised when administering promethazine to children as there is potential for central and obstructive apnoea and reduced arousal. Excessive dosages of antihistamines in children may cause hallucinations, convulsions and sudden death.

Background:

THERAPEUTIC INDICATIONS

- Allergies: Treatment of allergic conditions including some allergic reactions to drugs, urticaria and allergic contact dermatitis, and allergic reactions to insect bites and stings.
- Upper respiratory tract: Relief of excessive secretion in the upper respiratory tract as a result of hayfever and allergic rhinitis.
- Nausea and vomiting: Antiemetic for vomiting from various causes, including postoperative vomiting, irradiation sickness, drug induced nausea and motion sickness.
- Sedation: For short term use in adults under the advice of a doctor or pharmacist. Do not use or more than 7 to 10 consecutive days.
- Other: Promethazine can be used as a preanaesthetic medication for the prevention and control of post operative vomiting.

References:

Medasafe ([Click here](#))