

Wyeth Pharmaceuticals
500 Arcola Rd
Collegeville, PA
(800) 934-5556



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Dear Health Care Professional:

We are writing to make you aware of the latest information on labeling changes to the **CONTRAINDICATIONS**, **WARNINGS/Use in Pediatric Patients**, and **DOSAGE AND ADMINISTRATION** sections of the prescribing information for Phenergan (promethazine hydrochloride) Tablets and Suppositories.

Based on a review of adverse events for Phenergan in pediatric patients, the Food and Drug Administration has requested that the following changes, shown here underlined, be made to the product prescribing information.

CONTRAINDICATIONS

Phenergan Tablets and Suppositories are contraindicated for use in pediatric patients less than two years of age.

WARNINGS

PHENERGAN SHOULD NOT BE USED IN PEDIATRIC PATIENTS LESS THAN 2 YEARS OF AGE BECAUSE OF THE POTENTIAL FOR FATAL RESPIRATORY DEPRESSION. POSTMARKETING CASES OF RESPIRATORY DEPRESSION, INCLUDING FATALITIES, HAVE BEEN REPORTED WITH USE OF PHENERGAN IN PEDIATRIC PATIENTS LESS THAN 2 YEARS OF AGE. A WIDE RANGE OF WEIGHT-BASED DOSES OF PHENERGAN HAVE RESULTED IN RESPIRATORY DEPRESSION IN THESE PATIENTS.

CAUTION SHOULD BE EXERCISED WHEN ADMINISTERING PHENERGAN TO PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER. IT IS RECOMMENDED THAT THE LOWEST EFFECTIVE DOSE OF PHENERGAN BE USED IN PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER AND CONCOMITANT ADMINISTRATION OF OTHER DRUGS WITH RESPIRATORY DEPRESSANT EFFECTS BE AVOIDED.



WARNINGS

Use in Pediatric Patients

PHENERGAN TABLETS AND SUPPOSITORIES ARE CONTRAINDICATED FOR USE IN PEDIATRIC PATIENTS LESS THAN TWO YEARS OF AGE.

CAUTION SHOULD BE EXERCISED WHEN ADMINISTERING PHENERGAN TABLETS AND SUPPOSITORIES TO PEDIATRIC PATIENTS 2 YEARS OF AGE AND OLDER BECAUSE OF THE POTENTIAL FOR FATAL RESPIRATORY DEPRESSION. RESPIRATORY DEPRESSION AND APNEA, SOMETIMES ASSOCIATED WITH DEATH, ARE STRONGLY ASSOCIATED WITH PROMETHAZINE PRODUCTS AND ARE NOT DIRECTLY RELATED TO INDIVIDUALIZED WEIGHT-BASED DOSING, WHICH MIGHT OTHERWISE PERMIT SAFE ADMINISTRATION. CONCOMITANT ADMINISTRATION OF PROMETHAZINE PRODUCTS WITH OTHER RESPIRATORY DEPRESSANTS HAS AN ASSOCIATION WITH RESPIRATORY DEPRESSION, AND SOMETIMES DEATH, IN PEDIATRIC PATIENTS.

ANTIEMETICS ARE NOT RECOMMENDED FOR TREATMENT OF UNCOMPLICATED VOMITING IN PEDIATRIC PATIENTS, AND THEIR USE SHOULD BE LIMITED TO PROLONGED VOMITING OF KNOWN ETIOLOGY. THE EXTRAPYRAMIDAL SYMPTOMS WHICH CAN OCCUR SECONDARY TO PHENERGAN TABLETS AND SUPPOSITORIES ADMINISTRATION MAY BE CONFUSED WITH THE CNS SIGNS OF UNDIAGNOSED PRIMARY DISEASE, e.g., ENCEPHALOPATHY OR REYE'S SYNDROME. THE USE OF PHENERGAN TABLETS AND SUPPOSITORIES SHOULD BE AVOIDED IN PEDIATRIC PATIENTS WHOSE SIGNS AND SYMPTOMS MAY SUGGEST REYE'S SYNDROME OR OTHER HEPATIC DISEASES.



DOSAGE AND ADMINISTRATION

Phenergan Tablets and Phenergan Rectal Suppositories are contraindicated for children under 2 years of age (see **WARNINGS—Black Box Warning and **Use in Pediatric Patients**).**

Please see enclosed Prescribing Information.

If you require further information, please contact Global Medical Communications at 1-800-934-5556.

Regards,

Joseph Camardo, MD
Senior Vice President
Global Medical Affairs