

CODOPALM[®] Antihistaminic Syrup

CLINICAL PHARMACOLOGY

Promethazine HCl is an H₁ receptor blocking agent. In addition to its antihistaminic action, it provides clinically useful sedative and antiemetic effects.

INDICATIONS AND USAGE

CODOPALM[®] syrup is useful for relieving allergy symptoms, including hives or runny nose. It is used to prevent and control nausea and vomiting during and after surgery. It is also used to help produce light sleep, prevent and treat motion sickness; or treat pain after surgery, in combination with other medicines. CODOPALM[®] syrup is a phenothiazine antihistamine. It works by blocking histamine, which decreases the symptoms of allergies and helps decrease nausea and vomiting.

CONTRAINDICATIONS

CODOPALM[®] syrup is contraindicated in individuals known to be hypersensitive or to have had an idiosyncratic reaction to promethazine. It is also contraindicated in patients receiving MAO inhibitors therapy or with lower respiratory diseases including asthma.

CODOPALM[®] syrup is contraindicated for use in pediatric patients less than two years of age because of the potential for fatal respiratory depression.

WARNINGS

CODOPALM[®] may cause drowsiness. Patients should be cautious when being engaged in activities requiring mental alertness. Avoid concomitant use of alcohol or other CNS depressants.

PRECAUTIONS

Use with caution in patients with narrow-angle glaucoma, prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstruction and bladder-neck obstruction, cardiovascular disease or with impairment of liver function. Use with extreme caution in elderly patients.

Pediatrics Avoid excessively large doses because the promethazine component could cause hallucinations, convulsions, and sudden death. Parent should use care in giving the drug to children older than 2 years.

Pregnancy / Nursing Mothers

CODOPALM[®] syrup should not be used unless, in the judgment of the physician, the potential benefits outweigh possible hazards

ADVERSE REACTIONS

Drowsiness, blurred vision, dizziness, nausea, vomiting, dryness of the mouth are most frequently reported. Other side effects include fatigue, asthma, respiratory depression and apnea, photosensitivity and extrapyramidal reactions.

DOSAGE AND ADMINISTRATION

CODOPALM[®] syrup is contraindicated for children less than 2 years of age

It is strongly recommended that an accurate measuring device be used.

INDICATIONS	CHILDREN (Thru 12 years)	Adults (From 12 years)
Allergy	6.25 mg 4 times as needed	25 mg before retiring Or 6.25 - 12.5 mg 3 times daily Or 12.5 mg before meals and on retiring
Motion Sickness	12.5 - 25 mg twice daily	25mg twice daily: - 25 mg: ½ - 1 h before travel - 25 mg: 12 hours later if needed
Nausea and Vomiting	0.5 mg / 0.5 kg of body weight	12.5 - 25 mg repeated at 4 to 6 hours intervals
Sedation	12.5 - 25 mg at bedtime	25 - 50 mg for nighttime
Pre- and Postoperative Use	12.5 - 25 mg the night before surgery	50 mg the night before surgery

AVAILABILITY

Syrup Bottle of 100 ml containing Promethazine HCL 5 mg in each teaspoonful (5 ml).

STORAGE CONDITIONS

Keep tightly closed and protect from light.

Store at controlled room temperature, between 20°C and 25°C.

THIS IS A MEDICINE

- Medicines are products which affect your health, and failure to follow the instructions may be dangerous for you.
- Follow your doctor's advice carefully, the method of use, and the instructions of the pharmacist who sold you the medicine.
- Your doctor and pharmacist are expert in the use of medicines, and their benefits and risks.
- Do not stop your course of treatment early unless advised to do so by your doctor or pharmacist.
- Do not repeat the same prescription without consulting your doctor.

KEEP MEDICINES OUT OF THE REACH OF CHILDREN

