

**GUAIFENESIN + PHENYLEPHRINE HCl +
CHLORPHENAMINE MALEATE**

PLEURAGEX
100 mg/5 mg /2 mg per 5 mL Syrup
EXPECTORANT/DECONGESTANT/
ANTIHISTAMINE

FORMULATION:

Each 5 mL (one teaspoonful) contains:
Guaifenesin 100 mg
Phenylephrine Hydrochloride 2 mg
Chlorphenamine Maleate 5 mg

DESCRIPTION:

PLEURAGEX SYRUP is a combination of Guaifenesin + Phenylephrine Hydrochloride + Chlorphenamine through the rational combination offers effective and fast relief of cough nasal congestion and allergic condition due to colds, allergy and bronchitis.
Guaifenesin helps loosen and clear the bronchial passages of thickened mucus and aids expectorant.
PLEURAGEX SYRUP is a clear, red, syrupy liquid in cherry flavor. Boston round, Amber Bottle with Aluminum Cap x 60 mL and 120 mL (Box 1's).

WHAT IS IN THE MEDICINE?

PLEURAGEX SYRUP is a combination of Guaifenesin + Phenylephrine + Chlorphenamine through the rational combination offers effective and fast relief of cough nasal congestion and allergic condition due to colds, allergy and bronchitis.

Phenylephrine Hydrochloride a nasal congestant, clear obstructive air passages and nasal sinuses due to congestion making breathing easier. It also reduces postnasal drip.

Chlorphenamine Maleate an anti-allergy relieves symptoms such as runny-nose, sneezing and itchy watery eyes.

Guaifenesin helps loosen and clear the bronchial passages of thickened mucus and aids expectorant.

STRENGTH OF MEDICINE: See Formulation

WHAT IS THE MEDICINE USED FOR?

For the symptomatic relief of cough nasal congestion and allergic condition due to colds, allergy and bronchitis. It is also antihistamine.

This medicine is used for the relief of clogged nose, runny nose, postnasal drip, itchy and watery eyes, sneezing, allergic rhinitis and sinusitis. It also help s decongest sinus openings and passages.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Three to four times daily.
Children: 2.5 to 5.0 mL (1/2 to 1 teaspoonful)
Adults: 10 mL (2 teaspoonfuls) Or as prescribed by the physician.

WHEN SHOULD YOU NOT TAKE PLEURAGEX SYRUP?

Do not take **Pleuragex Syrup**:
* If you allergic to any of the ingredients of this medicine.
Talk to your doctor, nurse or pharmacist before taking if:
* you have high blood pressure or severe heart disease unless recommended by a doctor.
* If you have anemia, kidney or liver disease, unless recommended by a doctor.
* If you are pregnant or breastfeeding.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

CHLORPHENAMINE MALEATE may cause drowsiness and dulling of mental alertness.
Minor and transient effect dryness of the mouth, nervousness and irritability may occur. Do not use more than directed, Avoid alcoholic beverages, sedatives and tranquilizers as they may enhance drowsiness. Stop use and consult a doctor if nervousness, dizziness or sleeplessness occur.

UNDESIRABLE EFFECTS:

Phenylephrine Hydrochloride
Psychiatric disorders: Anxiety (Feeling of easiness), insomnia/sleeplessness and nervousness
Nervous system disorder: Dizziness, restlessness, tremor (muscle shaking)
Cardiac disorder: Arrhythmia (irregular heartbeat), palpitation.
Vascular disorders: Increased high blood pressure, pallor.
Respiratory, Thoracic and mediastinal disorders: Respiratory distress (noisy, congested breathing).
General disorders and administration site conditions: Weakness
Chlorphenamine Maleate: Chlorphenamine Maleate may cause sleepiness and drowsiness.
Psychiatric disorders: Insomnia/sleeplessness, nervousness.
Nervous system disorders: Headache, tremor (muscle shaking)
Eye disorders: Blurred vision, visual disturbance
Ear and Labyrinth disorders: Tinnitus (ringing in their ears).
Cardiac disorders: Chest tightness
Vascular disorders: increased or decreased blood pressure.
Gastrointestinal disorders: Constipation, diarrhea, gastrointestinal discomfort, nausea and vomiting.

Musculoskeletal and connective tissues disorders: Muscle weakness

Renal and urinary disorders: Difficulty of urination

General disorders and administration site conditions: Dryness of the mouth, nose, and throat, irritability

Guaifenesin Drowsiness.

Nervous system disorders: Dizziness, headache

Gastrointestinal disorders: Stomach pain, Nausea, vomiting

General disorders and administration site conditions: Decreased uric acid levels. Rashes.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Do not use this product together with sympathomimetic agents (e.g., epinephrine) and general anesthetics (e.g. halothane) because of the possibility to increase toxicity.

Concurrent administration with medicines for depression such as monoamine oxidase (MAO) inhibitors (e.g., selegiline, moclobemide) and tricyclic antidepressant (e.g., amitriptyline, imipramine) may result a hypertensive crisis (sudden severe increase blood pressure that can lead to stroke).

Taking alpha-adrenergic blocking agent (e.g., phenothiazine drugs, phentolamine) before the administration of this product may decrease the effect of phenylephrine. Concomitant use of beta-adrenergic agent blocking agent (e.g., Propranolol) and methyldopa may cause an increase of blood pressure.

Medicines that cause sedation such as anxiolytics (e.g., amprazolam, diazepam) and hypnotics (e.g., zolpidem) may potentiate drowsiness.

Guaifenesin helps to cough up mucus through the mouth. It helps in loosening chest and throat congestion. It is also used in combination with pseudoephedrine and dextromethorphan to treat cough, sinus congestion, stuffy nose, chest congestion due to allergies, flu, and the common cold. If this medicine is used with MAO inhibitors such as linezolid, rasagiline, selegiline, isocarboxazid, phenelzine, and tranlycypromine, it may cause a dangerous drug interaction.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If the patient misses a dose, just take the next dose if still needed for the condition being treated, and the subsequent doses at the recommended time or schedule (i.e., every 6 hrs). Do not double the dose.

SIGNS AND SYMPTOMS OF OVERDOSE:

Phenylephrine Hydrochloride:
Increased blood pressure, headache, seizures, palpitation, paresthesia (sensation of tingling, pricking or numbness of the skin), vomiting, cerebral hemorrhage (bleeding from a ruptured blood vessel in the brain).

Chlorphenamine Maleate:
Extreme sleepiness or prolonged drowsiness, Weakness, Hallucination, Convulsion, Agitation, Irritability, Tachycardia, Coma

Guaifenesin
Difficulty in breathing, swelling of the face, neck, tongue or throat (these are signs of a severe allergic reaction). Gastrointestinal discomfort, nausea and vomiting have occasionally been reported with Guaifenesin, particularly in very large doses.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you have taken more than the recommended dosage, consult a doctor or contact a Poison Center/Center right away.

HOW SHOULD YOU KEEP THIS MEDICINE?

Store at temperatures not exceeding 30°C.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Before taking this medication tell your doctor if you have:
High blood pressure or any type of a heart problems
Glaucoma, Thyroid problems, Diabetes, Liver or Kidney disease, Enlarge prostate, bladder problems or difficulty urinating.

ADR Reporting Statement:

For suspected adverse drug reaction, report to FDA: www.gov.ph
Patient must seek medical attention immediately at the first sign of any adverse drug reaction.

AVAILABILITY:

Boston Round Amber Bottle with Aluminum Cap x 60 mL and 120 mL in a box.

FDA Registration No.: DR-XY44106

SHELF-LIFE - 36 Months

DATE OF FIRST AUTHORIZATION/RENEWAL OF AUTHORIZATION

January 17, 2020

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