Phenylpropanolamine HCl
Chlorphenamine Maleate
Paracetamol

Decolgen® Forte

25 mg / 2 mg / 500 mg TABLET
Nasal Decongestant / Antihistamine / Analgesic-Antipyretic

FORMULATION

Each tablet contains:

Phenylpropanolamine HCl	25 mg
Chlorphenamine Maleate	2 mg
Paracetamol	500 mg

PRODUCT DESCRIPTION

Phenylpropanolamine HCl + Chlorphenamine Maleate + Paracetamol (Decolgen® Forte) tablet is a yellow, round, convex tablet with Westmont insignia on one side and flat, plain, bevel-edged on the other side.

WHAT IS IN THE MEDICINE?

This medicine contains Phenylpropanolamine HCl, Chlorphenamine Maleate and Paracetamol.
Phenylpropanolamine HCl, a nasal decongestant, clears obstructed and congested air passages making breathing easier. It decongests stuffy nose and clogged nasal sinuses.
Chlorphenamine Maleate, an anti-allergy, relieves symptoms of allergy such as runny nose, sneezing, and itchy, watery eyes.
Paracetamol is an effective fever reducer and pain reliever.

STRENGTH OF THE MEDICINE See Formulation

WHAT IS THIS MEDICINE USED FOR?

This medicine is used for the relief of clogged nose, runny nose, postnasal drip, itchy and watery eyes, sneezing, headache, body aches, and fever associated with the common cold, allergic rhinitis, sinusitis, flu, and other minor respiratory tract infections. It also helps decongest sinus openings and passages.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Adults and children 12 years and older: Orally, 1 tablet every 6 hours, or, as recommended by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

- If you are allergic to any ingredient in the product
- 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

UNDESIRABLE EFFECTS

Phenylpropanolamine may cause sudden, persistent, severe headache, nervousness, restlessness, insomnia/sleeplessness, dizziness, anxiety, confusion, high blood pressure, palpitation, chest tightness, tremor, agitation, irritability, aggressiveness (particularly in young children), nausea, and blurred vision.
Chlorphenamine Maleate may cause sleepiness and drowsiness. Other undesirable effects include muscle weakness, gastrointestinal discomfort, nausea, vomiting, diarrhea or constipation, dryness of the mouth, nose, and throat, difficulty urinating, ringing in the ears, visual disturbance, blurred vision, insomnia/sleeplessness, tremor, nervousness, irritability, chest tightness, increased or decreased blood pressure, and headache.
Paracetamol, when taken within the recommended dose and duration of treatment, has low incidence of side effects. Skin rashes and minor stomach and intestinal disturbances have been reported.

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

Do not use this product together with sympathomimetic agents (e.g., Epinephrine, etc.) and general anesthetics (e.g., Halothane, etc.) because of the possibility for increased toxicity.
Concurrent administration with medicines for depression (e.g., Amitriptyline, Imipramine, Sertraline, Moclobemide, etc.) may result in hypertensive crisis (sudden, severe increase in blood pressure that can lead to stroke).
The absorption of Paracetamol may be accelerated by Metoclopramide or Domperidone and reduced by Cholestyramine.
Medicines which stimulate the enzymes responsible for the metabolic activation of Paracetamol such as medicines for convulsion (e.g., Phenobarbital, etc.) may increase susceptibility to the harmful effects to the liver.

Warfarin, a blood thinning medicine; an increase in the International Normalized Ratio (INR), which may serve as a sign of increased risk for bleeding, may be observed when using paracetamol and warfarin at the same time. Paracetamol increases the anticoagulation effect of warfarin.
Tell your doctor about other medicines you are taking, especially other medicines for cough, cold, allergy, pain, or fever.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss 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 hours).
Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

Keep the product out of reach and sight of children. Store at temperatures not exceeding 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE

Phenylpropanolamine HCl

Fast heart rate (tachycardia); Irregular heart beat (arrhythmia); High blood pressure; Excitation; Seizures; Enlargement of the pupils; Cases of heart attack, stroke, intracranial bleeding/cerebral hemorrhage (bleeding from a ruptured blood vessel in the brain), and death have also been reported

Chlorphenamine Maleate

Extreme sleepiness or prolonged drowsiness; Weakness; Hallucination; Convulsion; Agitation; Irritability; Tachycardia; Coma

Paracetamol

Overdosage of Paracetamol usually involves 4 phases with the following signs and symptoms:

I. Eating disorder, nausea, vomiting, malaise, and excessive sweating
II. Right upper abdominal pain or tenderness, liver enlargement which may be characterized by abdominal discomfort of "feeling full", elevated bilirubin and liver enzyme concentrations, prolongation of prothrombin time, and occasionally decreased urine output
III. Eating disorder, nausea, vomiting, and malaise recur and signs of liver (e.g., jaundice) and possibly kidney failure
IV. Recovery or progression to fatal complete liver failure

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 control center right away, even if you seem well, because of the risk of delayed, serious liver damage. Quick medical attention is important for adults as well as for children even if you do not notice any signs or symptoms.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

- Use with caution in patients with high blood pressure, toxic goiter, benign prostatic hypertrophy, heart rate irregularity, glaucoma, and in those taking antidepressants.
- Patients with heart disease and uncontrolled/untreated high blood pressure should consult a doctor prior to taking Phenylpropanolamine.

- ***Liver Warning:*** This product contains Paracetamol. Severe liver damage may occur if you take:
  - More than 4 g of Paracetamol in 24 hours, which is the maximum daily amount;
  - With other medicines containing Paracetamol (or acetaminophen);
  - 3 or more alcoholic drinks everyday while using this product.
- Do not use with any other medicine containing Paracetamol (prescription or nonprescription). If you are not sure whether a medicine contains Paracetamol, ask a doctor.
- Ask a doctor before use if the patient has liver or kidney disease.
- Ask a doctor before use if the patient is taking warfarin, a blood thinning medicine.
- May cause drowsiness; patients should observe caution while driving or performing other tasks requiring alertness.
- Do not take more than the recommended dose.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

- Before taking this medication, tell your doctor if you have:
  High blood pressure or any type of heart problems; Glaucoma; Thyroid problems; Diabetes; Liver or kidney disease; An enlarged prostate, bladder problems or difficulty urinating
- Stop use and ask a doctor if: Fever gets worse or lasts more than 3 days; New symptoms occur

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph.
By reporting undesirable effects, you can help provide more information on the safety of this medicine.

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AVAILABILITY:

In box of 100's (blister pack of 20's)

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL):

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