UNILAB

Phenylpropanolamine HCl Paracetamol

No-Drowse Decolgen®

25 mg / 500 mg Tablet
Reformulated
NASAL DECONGESTANT / ANALGESIC / ANTIPYRETIC

FORMULATION
Each tablet contains:

Phenylpropanolamine (as Hydrochloride)	25 mg
Paracetamol	500 mg

PRODUCT DESCRIPTION
Phenylpropanolamine hydrochloride + Paracetamol (No-Drowse Decolgen®) tablet is a yellow, elliptical-convex, 0.662" x 0.300" in diameter, plain tablet, debossed with "DECOLGEN" on one side and bisected line on the other side.

WHAT IS IN THE MEDICINE?
This medicine contains phenylpropanolamine HCl and paracetamol.
Phenylpropanolamine HCl, a nasal decongestant, clears obstructed air passages and nasal sinuses due to congestion making breathing easier. It also reduces postnasal drip.
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, postnasal drip, headache, body aches, and fever associated with the common cold, 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 HCl
Psychiatric disorders: Aggressiveness (particularly in young children), anxiety (feeling of uneasiness), confusion, insomnia/sleep disturbance, nervousness
Nervous system disorders: Agitation, dizziness, restlessness; sudden, persistent, severe headache, tremor (muscle shaking)
Eye disorders: Blurred vision
Cardiac disorders: Chest tightness, palpitation
Vascular disorders: High blood pressure
Gastrointestinal disorders: Nausea
General disorders and administration site conditions: Irritability
Paracetamol
Paracetamol, when taken within the recommended dose and duration of treatment, has low incidence of side effects.
Blood and lymphatic system disorders: Changes in the number of white blood cells and platelets such as agranulocytosis (decrease in the number of granulocytes), leukopenia (decrease in the number of leukocytes), neutropenia (decrease in the number of neutrophils), pancytopenia (deficiency of all cellular elements in the blood), thrombocytopenia (decrease in the number of platelets)
Immune system disorders: Allergic reactions which may cause difficulty in breathing, skin rash, angioedema (swelling of the face or throat)
Gastrointestinal disorders: Minor stomach and intestinal disturbances
Skin and subcutaneous tissue disorders: Rare cases of serious skin reactions (i.e., Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalized exanthematous pustulosis) which may include symptoms such as skin reddening, blisters or rash

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 for increased toxicity.
Concurrent administration with medicines for depression such as monoamine oxidase (MAO) inhibitors (e.g., selegiline, moclobemide) and tricyclic antidepressants (e.g., amitriptyline, imipramine) may result in hypertensive crisis (sudden, severe increase in blood pressure that can lead to stroke).
Combined use of phenylpropanolamine and caffeine may produce an additive increase in blood pressure. Severe, life threatening, and occasionally fatal hypertensive reactions have been reported.
Paracetamol, when used together with warfarin (a blood-thinning medicine), may cause an increase in the International Normalized Ratio (INR), which may serve as a sign of increased risk for bleeding. Paracetamol increases the anticoagulation effect of warfarin.
Medicines which stimulate the enzymes responsible for the metabolic activation of paracetamol such as medicines for convulsion (e.g., phenobarbital, phenytoin) may increase susceptibility to the harmful effects to the liver.
The absorption of paracetamol may be accelerated by metoclopramide or domperidone and reduced by cholestyramine.
Tell your doctor about other medicines you are taking (i.e., other medicines for cough, cold, allergy, pain, or fever, especially other paracetamol-containing products).

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 30ºC.

SIGNS AND SYMPTOMS OF OVERDOSAGE
Phenylpropanolamine HCl
Signs and symptoms of phenylpropanolamine overdosage include tachycardia, arrhythmia (irregular heart beat), high blood pressure, excitation, enlargement of the pupils. Cases of heart attack, stroke, intracranial hemorrhage/cerebral hemorrhage (bleeding from a ruptured blood vessel in the brain), seizures, and death have also been reported.
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 failure (e.g., jaundice) and possibly kidney failure and cardiomyopathy (disorder of the heart muscle) may develop
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:
  - o An adult or child 12 years and older takes more than 4 g of paracetamol in 24 hours, which is the maximum daily amount;
  - o Taken with other medicines containing paracetamol (or acetaminophen);
  - o An adult has 3 or more alcoholic drinks everyday while using this product.
- Do not use with any other medicine containing paracetamol or phenylpropanolamine (prescription or nonprescription). If you are not sure whether a medicine contains these two active ingredients, ask a doctor.
- Ask a doctor before use if you have liver or kidney disease.
- Ask a doctor before use if you are taking warfarin, a blood thinning medicine.
- 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:
  - o High blood pressure or any type of heart problems
  - o Glaucoma
  - o Thyroid problems
  - o Diabetes
  - o Liver or kidney disease
  - o An enlarged prostate, bladder problems or difficulty urinating
- Stop use and ask a doctor if:
  - o Fever gets worse or lasts more than 3 days
  - o 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 +632-8-**UNILAB**-1 (+632-8-**864522**-1) for Metro Manila or toll-free +1-800-10-UNILAB-1 for provinces, or e-mail productsafety@unilab.com.ph.
By reporting undesirable effects, you can help provide more information on the safety of this medicine.

UNILAB Consumer Care
8-UNILAB-1
8-864522-1
Provincial Toll Free: 1-800-10-8645221
Email: info@unilab.com.ph
Website: www.unilab.com.ph

AVAILABILITY: In box of 100 tablets (blister pack x 10's), in envelope of 5 tablets

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