PARACETAMOL PHENYLPROPANOLAMINE HCl CHLORPHENAMINE MALEATE

Rx

RESTTAB

325 mg/25 mg/4 mg
CAPSULE
ANALGESIC / ANTIPYRETIC
NASAL DECONGESTANT / ANTIHISTAMINE

FORMULATION:
Each capsule contains:
Paracetamol..... 325mg
Phenylpropanolamine Hydrochloride..... 25mg
Chlorphenamine Maleate..... 4mg

DESCRIPTION:
Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occuring about 10 to 60 minutes after oral administration. Paracetamol distributed into most body tissues.
Phenylpropanolamine is given by mouth as the hydrochloride for the symptomatic treatment of nasal congestion. It is frequently used in combination preparations for the relief of cough and cold symptoms.
Chlorphenamine Maleate, an alkylamine derivative, is a sedating antihistamine that causes a moderate degree of sedation; it also has anti muscarinic activity.

INDICATION:
For the relief of clogged nose, runny nose, postnasal drip, itchy and watery eyes, sneezing, headaches, and fever associated with the common cold, allergic rhinitis, sinusitis, flu and other minor respiratory tract infections. It is also helps decongest sinus openings and passages.

DOSAGE:
One capsule 3 to 4 times a day or as prescribed by the physician.

PHARMACOKINETICS:
Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma-Protein binding is negligible at usual therapeutic concentration but increases with increasing concentrations. The eliminations half-life of paracetamol varies from about 1 to 3 hours. Paracetamol is metabolized predominantly in the liver and excreted in the urine mainly as the glucuronide and sulfate conjugates. Less than 5% is excreted as unchanged paracetamol. A minor hydroxylated metabolite (N-acetyl-p-benzoquinoneimine), which is usually produced in very small amounts by mixed function oxidase in the liver and kidney and which is usually detoxified by conjugation with glutathione, may accumulate following paracetamol overdosage and cause tissue damage.

Phenylpropanolamine completely absorbed from the gastrointestinal tract, peak plasma concentration being achieved about 1 or 2 hours after oral administration. It undergoes some metabolism in the liver, to an active hydroxylated metabolite, but up to 80% to 90% of a dose is excreted unchanged in the urine within 24 hours. The half-life has been reported to be about 3 to 5 hours.

Chlorphenamine maleate is absorbed relatively slowly from the gastrointestinal tract, peak plasma concentrations occurring about 2.5 to 6 hours after administration by mouth. Bioavailability is low, values of 25 to 50% having been reported. Chlorphenamine appears to undergo considerable first-pass metabolism. About 70% of Chlorphenamine in the circulation is bound to plasma proteins. There is wide inter individual variation in the pharmacokinetics ofChlorphenamine; values ranging from 2 to 43 hours have been reported for the half-life. Chlorphenamine is widely distributed in the body, including passage into the Central Nervous system.

ADVERSE EFFECTS:
Gastrointestinal upsets, drowsiness, dizziness, dry mouth, difficulty in micturition, sweating, reduced appetite, epileptiformseizure(largedoses).

PRECAUTION:
Glaucoma, cardiac, renal or hepatic disease, diabetes, asthma, pregnancy, may impairability to drive or operate machinery, alcoholics.

CONTRAINDICATIONS:
Hyperthyroidism, hypertension, coronary disease; Cardiovascular disease, ventricular arrthythmia, acute angle glaucoma, pheochromocytoma. Monoamine Oxidase Inhibitors therapy nephropathy.

DRUG INTERACTIONS:
Antihistamines may potentiate other Central Nervous System depressants. Possible Additive effects with Monoamine Oxidase Inhibitors, rauwolfia alkaloids, tricyclic antidepressants, ganglionic-blocking agents and halogenated hydrocarbon general anesth. Prolonged use of paracetamol may potentiate effects of oral anticoagulants. Phenothiazines.

WARNING:
*PHENYLPROPANOLAMINE HYDROCHLORIDE - Patients with the following health conditions should be careful in taking PPA; 1) High blood pressure 2) Toxic goiter, 3) Benign prostatic hyperthropy, 4)Heart rate irregularity 5) Glaucoma and 6) If taken antidepressant, Patient with heart disease and uncontrolled/untreated high blood pressure should consult the doctor prior taken PPA.

SHELF-LIFE : 36 Months

CAUTION:
Foods, Drugs, Devices and Cosmetic prohibits dispensing without prescription.

STORAGE CONDITION:
Store at Temperatures Not Exceeding 30°C.

AVAILABILITY:
Aluminum Foil/PVC Clear, Blister pack x 10's (Box of 100 capsules)

Manufactured by:
SAN MARINO *Laboratories* CORP.
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Brgy. Javalera, Gen. Trias, Cavite
For: