PHENYLEPHRINE HCl CHLORPHENAMINE MALEATE PARACETAMOL

Neozep® Forte
10 mg / 2 mg / 500 mg Tablet

Neozep®
2.5 mg / 0.5 mg / 125 mg per 5 mL Syrup

Nasal Decongestant / Antihistamine / Analgesic - Antipyretic

FORMULATIONS

Each tablet contains:
- Phenylephrine HCl ..... 10 mg
- Chlorphenamine Maleate ..... 2 mg
- Paracetamol ..... 500 mg

Each 5 mL (1 teaspoonful) syrup contains:
- Phenylephrine HCl ..... 2.5 mg
- Chlorphenamine Maleate ..... 0.5 mg
- Paracetamol ..... 125 mg

PRODUCT DESCRIPTIONS

Phenylephrine HCl + Chlorphenamine Maleate + Paracetamol (Neozep® Forte) Tablet is a green and white, elliptical-convex, 0.662" x 0.300" in diameter, two-layer tablet, debossed with "NEOZEP" on the green layer, and plain on the white layer.

Phenylephrine HCl + Chlorphenamine Maleate + Paracetamol (Neozep®) Syrup is a dark pink, clear syrup with fruity strawberry odor and candy strawberry taste.

WHAT IS IN THE MEDICINE?

These medicines contain Phenylephrine HCl, Chlorphenamine Maleate and Paracetamol.

Phenylephrine HCl, a nasal decongestant, clears obstructed air passages and nasal sinuses due to congestion making breathing easier. It also reduces postnasal drip.

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 Formulations

WHAT IS THIS MEDICINE USED FOR?

These medicines are 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. They also help decongest sinus openings and passages.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE? These medicines should be taken orally (by mouth).

Age Group	Dose of Phenylephrine HCl + Chlorphenamine Maleate + Paracetamol every 6 hours	
	TABLET	SYRUP
Adults and Children 12 years and older	1 tablet	15 mL (3 teaspoonfuls)
Children 7 to 12 years old	-	10 mL (2 teaspoonfuls)
Children 2 to 6 years old	-	5 mL (1 teaspoonful)
	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

Phenylephrine HCl may cause tremor (muscle shaking), restlessness, anxiety (feeling of uneasiness), insomnia/sleeplessness, nervousness, dizziness, increased blood pressure, palpitation, arrhythmia (irregular heart beat), weakness, respiratory distress (noisy, congested breathing), and pallor.

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, hypersensitivity reactions, changes in the number of white blood cells and platelets, 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).

Taking an adrenergic-blocking agent (e.g., Phenothiazine drugs, Phentolamine, Propranolol, etc.) before the administration of this product may decrease the effect of Phenylephrine.

The absorption of Paracetamol may be accelerated by metoclopramide or domperidone and absorption 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

Phenylephrine HCl
- 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

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

- Liver Warning: These products contain Paracetamol. Severe liver damage may occur if:
  - A child takes more than 5 doses in 24 hours, which is the maximum daily amount of Paracetamol;
  - An adult takes more than 4 g of Paracetamol in 24 hours, which is the maximum daily amount;
  - Taken with other medicines containing Paracetamol (or Acetaminophen);
  - An adult has 3 or more alcoholic drinks everyday while using these products.
- Do not use with any other medicine containing Paracetamol (prescription or nonprescription). If you are not sure whether 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

AVAILABILITY:

- Neozep® Forte Tablet* - In box of 500 tablets (blister strip x 10s) and envopack x 4 tablets (blister strip x 2's)
- Neozep® Syrup - In bottle of 60 mL

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): March 2013

*Manufactured by PT MEDIFARMA LABORATORIES
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