UNILAB

# PHENYLEPHRINE HCl PARACETAMOL + ZINC

## Neozep® Z+ Non-Drowsy 10mg / 325mg / 10mg Tablet

**Nasal Decongestant • Analgesic-Antipyretic • Mineral**

**FORMULATION**

Each tablet contains:

Phenylephrine HCl ..... 10 mg
Paracetamol ..... 325 mg
Zinc ..... 10 mg (equivalent to 27.446 mg Zinc Sulfate Monohydrate)

**PRODUCT DESCRIPTION**

Phenylephrine HCl + Paracetamol + Zinc (Neozep® Z+ Non-Drowsy) Tablet is a green with white speckle, 0.662" x 0.300" elliptical-shaped plain tablet, debossed with "NEOZEP" on one side and plain on the other side.

**WHAT IS IN THE MEDICINE?**

This medicine contains phenylephrine HCl, paracetamol and zinc.

Phenylephrine 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.

Zinc is an essential mineral required for the normal development and maintenance of the immune system. It helps regulate the activity of cells involved in immune function. Zinc may also help in alleviating symptoms reducing the severity and progression, leading to shorter duration of common cold.

Phenylephrine HCl + paracetamol + zinc, in an *in vitro* study (outside the living organism), was shown to maintain respiratory cell viability (ability to retain healthy cells) during viral infection which may aid in the recovery from viral infection/illness.

Phenylephrine HCl + paracetamol + zinc is expected to start taking effect in as fast as 15 minutes.

**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 and protect respiratory cells against common cold and flu viruses. It also provides zinc for treatment and prevention of mineral deficiency.

**HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?**

Adults: 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 of 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**

***Psychiatric disorders:*** Anxiety, insomnia/sleeplessness, nervousness
***Nervous system disorders:*** Dizziness, restlessness, tremor (muscle shaking)
***Cardiac disorders:*** Arrhythmia (irregular heart beat), palpitation
***Vascular disorders:*** Increased blood pressure, pallor
***Respiratory, thoracic and mediastinal disorders:*** Respiratory distress (noisy, congested breathing)
***General disorders and administration site conditions:*** Weakness

**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 reddening of the skin, rash, blisters and detachment of the upper surface of the skin have been reported with paracetamol.

**Zinc**

***Metabolism and nutrition disorders:*** Loss of appetite
***Psychiatric disorders:*** Drowsiness
***Nervous system disorders:*** Headache, metallic taste
***Gastrointestinal disorders:*** Abdominal pain/cramps, diarrhea, dyspepsia, gastritis, gastrointestinal discomfort/irritation, nausea, vomiting

**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).

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

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.

Zinc decreases the absorption of certain antibiotics such as quinolones (e.g., ciprofloxacin, levofloxacin, ofloxacin) and tetracyclines (e.g., doxycycline, tetracycline). Zinc salts should be given 2 hours after or 6 hours before antibiotics.

Concomitant intake of a bisphosphonate (e.g., alendronate, etidronate, risedronate) and zinc may decrease the absorption of both the bisphosphonate and zinc.

Zinc inhibits the absorption of copper and iron. Administer zinc and copper or iron as far apart as possible.

Additive effects are possible with concurrent administration of zinc and cholesterol medicines; use with caution.

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?**

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

**SIGNS AND SYMPTOMS OF OVERDOSAGE**

**Phenylephrine HCl**

- Increased blood pressure
- Seizures
- Paresthesia (sensation of tingling, pricking, or numbness of the skin)
- Cerebral hemorrhage (bleeding from a ruptured blood vessel in the brain)
- Headache
- Palpitation
- Vomiting

**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

**Zinc**

Signs of acute zinc toxicity (doses > 200 mg daily) include gastrointestinal pain/cramps, nausea, vomiting, and diarrhea, loss of appetite, headache, lethargy (sleepiness), muscle pains, and fever.

Prolonged zinc supplementation may cause impairment of copper and iron status, and anemia at doses > 50 mg/day; immune deficiency, reduced blood high-density lipoprotein (HDL) levels, and gastric erosion at doses > 150 mg daily.

Long-term (average 6.3 years) ingestion of supplemental zinc (80 mg/day) has also been linked to a significant increase in hospitalizations for urinary tract infections and kidney stones.

**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: 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.
- Allergy Alert: Paracetamol may cause severe skin reactions. Symptoms may include:
  - Skin reddening • Blisters • Rash
- If a skin reaction occurs, stop use and seek medical help right away.
- Do not use with any other medicine containing phenylephrine, chlorphenamine or paracetamol (prescription or nonprescription). If you are not sure whether a medicine contains these active ingredients, ask a doctor.
- This product provides the maximum daily intake of zinc when taken at the recommended dose of four times a day. To avoid excessive intake, refrain from using other supplements or medicines containing zinc. If you are not sure whether a medicine contains zinc, 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:
  - High blood pressure or any type of heart problems
  - Thyroid problems
  - Liver or kidney disease
  - Glaucoma
  - Diabetes
  - 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 +632-8-**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.

Availability: Box of 100's (in PVC/Blister Foil x 10's)
Date of First Authorization: 28 September 2021
Date of Revision of Patient Information Leaflet (PIL):

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