DIPHENHYDRAMINE HCl
PHENYLPROPANOLAMINE HCl

TUSERAN® NIGHT

12.5 mg / 12.5 mg per 5 mL Syrup

NIGHTTIME RELIEF FOR COLD & COUGH

ANTIHISTAMINE-ANTITUSSIVE
NASAL DECONGESTANT

FORMULATION
Each 5 mL (1 teaspoonful) Syrup contains:
Diphenhydramine HCl ..... 12.5 mg
Phenylpropanolamine HCl ..... 12.5 mg

PRODUCT DESCRIPTION
Diphenhydramine HCl 12.5 mg + Phenylpropanolamine HCl 12.5 mg (Tuseran® Night) per 5 mL is a clear, green, strawberry-mint flavored syrup.

WHAT IS IN THE MEDICINE?
This medicine contains diphenhydramine HCl and phenylpropanolamine HCl.
Diphenhydramine HCl, a cough suppressant (antitussive), acts centrally by depressing the cough center in the medulla of the brain and therefore elevates the threshold for coughing. Diphenhydramine HCl is also a sedating antihistamine which diminishes allergic symptoms by blocking histamine receptors.
Phenylpropanolamine HCl, a nasal decongestant, clears obstructed and congested air passages making breathing easier.

STRENGTH OF THE MEDICINE
See Formulation

WHAT IS THIS MEDICINE USED FOR?
This medicine is used for the relief of cough, clogged nose, runny nose, postnasal drip, sneezing, and itchy and watery eyes 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?
Orally, every 6 hours, or as recommended by a doctor.
Children 2 to 6 years old ..... 2.5 mL (1/2 teaspoonful)
7 to 12 years old ..... 5 mL (1 teaspoonful)
Adults and children over 12 years ..... 10 mL (2 teaspoonsful)

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?
- If you are allergic to any ingredient of the product
- If you have narrow angle glaucoma, high blood pressure, severe heart disease, history of stroke or intracranial hemorrhage, porphyria (a rare blood disease), stomach ulcer or obstruction of the gut or bladder, or kidney disease unless recommended by a doctor
- If you are pregnant or breastfeeding

UNDESIRABLE EFFECTS
Diphenhydramine may cause sedation, dizziness, tinnitus (ringing in the ears), fatigue (excessive tiredness), ataxia (lack of muscle coordination), blurred vision, diplopia (double vision), euphoria (feeling of great happiness or well-being), nervousness, and tremors (muscle shaking). Gastrointestinal effects include epigastric distress, nausea and vomiting, which may be reduced by taking diphenhydramine with meals. Other side effects include dryness of mouth and mucous secretions, palpitation (rapid and irregular heart beat), urinary tract dysfunction, and severe allergic reactions such as difficulty of breathing and swelling of the face, neck, tongue or throat.
Phenylpropanolamine may cause sudden, persistent, severe headache, nervousness, restlessness, insomnia/sleeplessness, dizziness, anxiety (feeling of uneasiness), confusion, high blood pressure, palpitation, chest tightness, tremor, agitation, irritability, aggressiveness (particularly in young children), nausea, and blurred vision.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
Do not use this product together with alcohol, medicines for anxiety or sleep disorder

(e.g., alprazolam, chlordiazepoxide, diazepam, temazepam, triazolam, etc.), medicines for depression (e.g., amitriptyline, imipramine, moclobemide, sertraline, etc.), other cold or allergy medicines, or any other medicines that cause drowsiness, sleepiness and relaxation because of the possibility for increased sedation.
Concurrent administration with monoamine oxidase inhibitors (MAOIs; e.g., phenelzine, selegiline, etc.) may result in hypertensive crisis (sudden, severe increase in blood pressure that can lead to stroke). Do not use this product in patients taking MAOIs or within two weeks after stopping a MAOI.
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. Do not use this product with beta-blockers (e.g., carvedilol, metoprolol, propranolol) as diphenhydramine may increase the amount of beta-blockers in the blood which may result in increased cardiovascular effects of these medicines.
Tell your doctor about other medicines you are taking (i.e., other medicines for cough, cold or allergy).

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
Mild cases of diphenhydramine overdose are mainly characterized by dry mouth, headache, nausea, tachycardia (fast heart rate), and urinary retention. In children, the clinical features include hallucinations, dilated pupils, fever, ataxia, and convulsions. Cardiorespiratory depression and coma may subsequently develop, with death occurring between 2 to 18 hours. Adults usually develop drowsiness first, then convulsion, and coma at a later stage. Signs and symptoms of phenylpropanolamine overdose 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.

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.

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.

- May cause drowsiness; patients should observe caution while driving or performing other tasks requiring alertness.
- Use with care in patients with breathing problems and chronic cough as with asthma or chronic obstructive pulmonary disease (COPD) as diphenhydramine might cause thickening of bronchial secretions that may result in obstruction of respiratory passages.
- Do not use with any other medicine containing diphenhydramine or phenylpropanolamine (prescription or nonprescription). If you are not sure whether a medicine contains these two active ingredients, ask a doctor.
- 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:
  - Asthma, emphysema, chronic bronchitis, or other lung diseases
  - High blood pressure or any type of heart problems
  - A history of or suffer seizures
  - Glaucoma
  - Thyroid problems
  - Diabetes
  - Liver or kidney disease
  - An enlarged prostate, bladder problems or difficulty urinating
- Stop use and ask a doctor if:
  - Symptoms do not improve
  - New symptoms appear

Trusted Quality Healthcare

AVAILABILITY: 60 mL Bottle

DATE OF REVISION OF PATIENT INFORMATION LEAFLET (PIL): December 11, 2013

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