Tussivan-N syrup

(Chlorpheniramine Maleate 0.02 gm + Phenylephrine HCl 0.1 gm +Dextromethorphan 0.073 gm as Dextromethorphan HBr 0.1 gm)/100 ml

Not used for children under 12 years old

DESCRIPTION:

Tussivan – N Syrup is an alcohol-free, red syrup with Orange flavor.

Each 5 ml contains:

Active ingredients:

Chlorpheniramine Maleate	1 mg
Phenylephrine HCl	5 mg
Dextromethorphan	3.65 mg
«As Dextromethorphan HBr»	5 mg

Antitussive/Nasal Decongestant/Antihistaminic syrup for oral administration.

Inactive ingredients:

Propylene glycol, Sugar, Benzoic acid , Citric acid anhydrous , Methyl paraben , Propyl paraben , Sodium citrate ,Carmoisine red 60%,Orange oil , Raspberry essence ,Cinnamon oil & Distilled water.

- Phenylephrine Hydrochloride is an orally effective nasal decongestant having the chemical name Benzenemethanol, 3-hydroxy-α-[(methylamino) methyl]-, hydrochloride (R)-. Its structure is as follows:

$C_9H_{13}NO_2 \cdot HCL$ 203.67

- Chlorpheniramine Maleate is an antihistaminic having the chemical name 2-Pyridinepropanamine, Y-(4-chlorophenyl)-N,N-dimethyl-, (Z)-2-butenedioate (1:1). Its structure is as follows:

$C_{16}H_{19}CLN_2 \cdot C_4H_4O_4$ 390.86

- Dextromethorphan Hydrobromide is an antitussive having the chemical name Morphinan, 3-methoxy-17-methyl-, (9α, 13α, and 14α)-, hydrobromide, monohydrate. Its structure is as follows:

$C_{18}H_{25}NO \cdot HBr \cdot H_2O$ 370.32

CLINICAL PHARMACOLOGY:

- Dextromethorphan hydrobromide acts centrally to elevate the threshold for coughing. It has no analgesic or addictive properties. The onset of antitussive action occurs in 15 to 30 minutes after administration and is of long duration.
- Phenylephrine hydrochloride is an α-adrenergic receptor agonist (sympathomimetic) which produces vasoconstriction by stimulating α-receptors within the mucosa of the respiratory tract. Clinically, phenylephrine shrinks swollen mucous membranes, reduces tissue hyperemia, edema, and nasal congestion, and increases nasal airway patency.
- Chlorpheniramine maleate is an antihistamine with anticholinergic (drying) and sedative side effects. Antihistamines appear to compete with histamine for cell receptor sites on effector cells. Chlorpheniramine maleate is a member of the alkylamine class of antihistamines, which are among the least sedating antihistamines.

INDICATIONS:

- Tussivan – N Syrup is indicated for the temporary relief of coughs and upper respiratory relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold.

CONTRAINDICATIONS:

- Hypersensitivity to any of the ingredients. Because of the drying effect on lower respiratory secretions, Tussivan – N Syrup is not recommended in the treatment of bronchial asthma. The product is also contraindicated in patients with severe hypertension, severe coronary artery disease, narrow-angle glaucoma, urinary retention, peptic ulcer, and in patients on MAO inhibitor therapy (or for 14 days after stopping MAOI therapy).

WARNINGS:

- A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur, or is accompanied by fever, rash, or persistent headache, consult a physician. Do not take this product for persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus) unless directed by a physician.
- Hypertensive crisis can occur with concurrent use of phenylephrine and monoamine oxidase (MAO) inhibitors (or for 14 days after stopping MAOI therapy), indomethacin or with beta-blockers and methyldopa. If a hypertensive crisis occurs, these drugs should be discontinued, and therapy to lower blood pressure should be instituted immediately. Fever should be managed by external cooling.
-Antihistamines may produce drowsiness or excitation, particularly in children and elderly patients. Do not exceed recommended dosage. Especially in infants and small children, antihistamines in overdosage may cause hallucinations, convulsions, and death.
- Tussivan –N syrup is not indicated in children under 12 years of age.

PRECAUTIONS:

General:

Because of its antihistamine component, Tussivan – N Syrup should be used with caution in patients with a history of bronchial asthma, gastrointestinal obstruction, or urinary bladder neck obstruction. Because of its sympathomimetic component, Tussivan – N Syrup should be used judiciously and sparingly in patients with hypertension, diabetes, heart disease, increased intraocular pressure, hyperthyroidism, or prostatic hypertrophy. Sympathomimetics may produce central nervous system stimulation with convulsions or cardiovascular collapse with accompanying hypotension.

Information for Patients:

- Antihistamines may impair mental and/or physical abilities required for the performance of potentially hazardous tasks, such as driving a vehicle or operating machinery. Patients should be cautioned accordingly.

Stimulants, such as phenylephrine, are banned and tested for by the U.S. Olympic Committee (USOC) and the National Collegiate Athletic Association (NCAA.)

Drug Interactions:

- Antihistamines have additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, antianxiety agents, etc.) When such combined therapy is contemplated, the dose of one or both agents should be reduced. The use of phenylephrine with other sympathomimetic amines and MAO inhibitors (or for 14 days after stopping MAOI therapy) may produce an additive elevation of blood pressure. MAO inhibitors (or for 14 days after stopping MAOI therapy) may prolong the anticholinergic effects of antihistamines

Usage in Pregnancy:

Teratogenic Effects

Pregnancy Category C

It is not known whether this product can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. It should be given to a pregnant woman only if clearly needed.

Nursing Mothers:

Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from this product, a decision should be made whether to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use:

Safety and effectiveness in the pediatric population, under 6, have not been established.

ADVERSE REACTIONS:

- The most frequent adverse reactions to Tussivan –N Syrup include sedation, dryness of mouth, nose and throat, thickening of bronchial secretions, and dizziness. Other adverse reactions may include:
- Dermatologic: Urticaria, drug rash, photosensitivity, and pruritus.
- Cardiovascular System: Hypotension, hypertension, cardiac arrhythmias.
- Central Nervous System: Disturbed coordination, tremor, irritability, insomnia, visual disturbances, weakness, nervousness, convulsions, headache, euphoria, and dysphoria.
- Gastrointestinal System: Epigastric discomfort, anorexia, nausea, vomiting, diarrhea or constipation.
- Genitourinary System: Urinary frequency, difficult urination.
- Respiratory System: Tightness of chest and wheezing, shortness of breath.
- Hematologic System: Hemolytic anemia, thrombocytopenia, agranulocytosis.

OVERDOSAGE AND TREATMENT OF OVERDOSAGE:

Dextromethorphan in toxic doses will cause drowsiness, ataxia, nystagmus, opisthotonos, and convulsive seizures. Symptoms of over dosage with phenylephrine include hypertension, headache, convulsions, cerebral hemorrhage, and vomiting. Effects of antihistamine over dosage may vary from central nervous system depression (sedation, apnea diminished mental alertness, cardiovascular collapse) to stimulation (insomnia, hallucinations, tremors, or convulsions) to death.

Treatment:

- Induce emesis if patient is alert and is seen prior to 6 hours following ingestion. Precautions against aspiration must be taken, especially in infants and small children. Gastric lavage may be carried out, although in some instances, tracheotomy may be necessary prior to lavage. Naloxone hydrochloride 0.005 mg/kg intravenously may be of value in reversing the CNS depression that may occur from an over dosage of dextromethorphan. CNS stimulants may counter CNS depression. Should CNS hyperactivity or convulsive seizures occur, intravenous short-acting barbiturates may be indicated. Hypertensive responses and/or tachycardia should be treated appropriately. Oxygen, intravenous fluids, and other supportive measures should be employed as indicated.

DOSAGE AND ADMINISTRATION:

Adults and children over 12 years

2 teaspoonfuls (10 mL) every 6 hours. Do not exceed 4 doses during a 24-hour period.

This product is not indicated for use in children under 12 years of age.

HOW SUPPLIED:

Carton box containing a brown glass bottle of 125 ml & inner leaflet.

WARNING: Keep this and all medications out of the reach of children. In case of accidental overdose seek professional assistance or contact a poison control center immediately.

STORAGE:

Store at temperature not exceeding 30° c

PHARMACIST:

Dispense in a tight, light-reistant container as defined in the USP/NF with a child-resistant closure.

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