TUSS-ONE™
Dextromethorphan Hydrobromide, Phenylephrine Hydrochloride and Chlorpheniramine Maleate Syrup

COMPOSITION
Each Teaspoonful (5 mL) contains:
Dextromethorphan hydrobromide IP .......... 10 mg
Chlorpheniramine maleate IP ............... 2 mg
Phenylephrine hydrochloride IP .......... 5 mg
Colour: ponceau 4R

FORMULA
TUSS-ONE Cough formula has doctor trusted formula which gives quick relief from cough, cold and blocked nose.

DESCRIPTION
TUSS-ONE Cough Syrup is a alcohol-free, Raspberry flavored syrup for oral administration for adults and for pediatric patients 2 years and older.
Dextromethorphan hydrobromide is an antitussive with the chemical name 3-Methoxy-17-methyl-9a, 13a, 14a - morphinan hydrobromide monohydrate.
Its structure is as follows:

Phenylephrine hydrochloride is a mydriatic and a decongestant with the chemical name: \( \text{(-)-m-Hydroxy-\alpha-[(methylamino)methyl]phenyl} \) alcohol hydrochloride.
Its chemical structure is as follows:

Chlorpheniramine maleate is an antihistamine with the chemical name: 2-Pyridinepropanamine, \( \gamma \)-(4-chlorophenyl)-N, N-dimethyl- (Z)-2-butenedioate (1:1).
Its chemical structure is as follows:
CLINICAL PHARMACOLOGY

Antitussive, Decongestant, Antihistaminic actions.

Dextromethorphan hydrobromide is a non-narcotic antitussive with effectiveness equal to codeine. It acts in the medulla oblongata to elevate the cough threshold. Dextromethorphan does not produce analgesia or induce tolerance, and has no potential for addiction. At usual doses, it will not depress respiration or inhibit ciliary action. Dextromethorphan is rapidly metabolized with transfer of the parent compound in blood and urine. About one-half of the administered dose is excreted in the urine as conjugated metabolites.

Phenylephrine hydrochloride is an oral sympathomimetic amine that acts as a decongestant to respiratory tract mucous membranes. While its vasoconstrictor action is similar to that of ephedrine, phenylephrine has less pressor effect. In normotensive adults, serum half-life for phenylephrine is 6 to 8 hours. Acidic urine is associated with faster elimination of the drug. About one-half of the administered dose is excrusted in the urine.

Chlorpheniramine maleate possesses H1 antihistaminic activity and mild anticholinergic and sedative effects. Peak plasma concentration is reached in 5 hours. Urinary excretion is the major route of elimination. The liver is assumed to be the major site of metabolic transformation.

Relieving symptoms of sinus congestion, runny nose, sneezing, itchy nose or throat, itchy or watery eyes, cough due to colds, upper respiratory infections, or allergies. It may also be used for other conditions as determined by your doctor.

TUSS-ONE syrup is a decongestant, antihistamine, and cough suppressant combination. The decongestant works by constraining blood vessels and reducing swelling in the nasal passages. The antihistamine works by blocking the action of histamine, which helps reduce symptoms such as watery eyes and sneezing. The cough suppressant works in the brain to help decrease the cough reflex to reduce a dry cough.

ABOUT COUGH

Cough is an important natural reflex and defense mechanism that helps to clear excessive secretions and prevent foreign matter from entering the airways. In short, Cough is an important way to keep your throat & airways clear.

TYPES OF COUGH

Some coughs are dry & often accompanied with other symptoms like nasal congestion, running nose, excessive sneezing, itchy watery eyes & throat irritation, while sometimes cough can be productive & bring phlegm, sputum or Mucus.

Cough can be either acute, subacute or chronic. Acute cough lasts up to 3 weeks max. Subacute cough lasts from 3 to 8 weeks, Chronic cough lasts more than 8 weeks.

INDICATIONS & USAGE

For relief of coughs and upper respiratory symptoms, including nasal congestion, associated with allergy or the common cold.

CONTRAINDICATIONS

Patients with hypersensitivity or idiosyncrasy to any of its ingredients.

Symptomaticmimetic amines are contraindicated in patients with severe hypertension, severe coronary artery disease and patients on monoamine oxidase (MAO) inhibitor therapy. Antihistamines are contraindicated in patients with narrow angle glaucoma, urinary retention, peptic ulcer and during an asthma attack.

Dextromethorphan should not be used in patients receiving a monoamine oxidase inhibitor (MAOI) for 2 weeks after stopping the MAOI drug.

WARNINGS

Do not exceed recommended dosage. Symptomimetic amines should be used judiciously and sparingly in patients with hypertension, diabetes, ischemic heart disease, hyperthyroidism, increased intracranial pressure. Symptomimetic amines may produce CNS stimulation with convulsions or cardiovascular collapse with accompanying hypotension. At doses higher than the recommended dose, nervousness, dizziness or sleeplessness may occur. Administration of dextromethorphan may be accompanied by Histamine release and should be used with caution in asthmatic children.

PRECAUTIONS

Information for Patients: Avoid alcohol and other CNS depressants while taking this product. Performance of potentially hazardous tasks such as driving a vehicle or operating machinery. Patients should be warned accordingly. Drug Interactions: Antihistamines may enhance the effects of tricyclic antidepressants, barbiturates, alcohol and other CNS depressants.

ADVERSE REACTIONS

Antihistamines may cause sedation, dizziness, diplopia, vomiting, diarrhea, dry mouth, headache, nervousness, nausea, anorexia, heartburn, weakness, polyuria and dysuria and, rarely, excitability in children.

OVERDOSE

Symptoms: predominant symptoms are excitation, hallucination, ataxia, incoordination, tremors, flushed face and fever. Convulsions, fixed and dilated pupils., Respiration is usually not seriously depressed; blood pressure is usually stable.

Central effects include restlessness, dizziness, tremor, hyperactive reflexes, talkativeness, irritability and insomnia, headache, flushing, palpitation, cardiac arrhythmia, hypertension with subsequent hypotension and circulatory collapse. Gastrointestinal effects include dry mouth, metallic taste, anorexia, nausea, vomiting, diarrhea and abdominal cramps.

DOSAGE & ADMINISTRATION

TUSS-ONE Cough Syrup - Adults and Children 12 years of age and older: 1 teaspoonful (5 mL) every 4 to 6 hours, not to exceed 6 teaspoonsful in 24 hours. Children 6 to under 12 years of age: 1/2 teaspoonful (2.5 mL) every 4 to 6 hours, not to exceed 3 teaspoonsfuls in 24 hours. Children 2 to under 6 years of age: 1/4 teaspoonful (1.25 mL) every 4 to 6 hours, not to exceed 1.5 teaspoonsfuls in 24 hours. Not recommended for use in children under 2 years of age. In mild cases or in particularly sensitive patients, less frequent or reduced doses may be appropriate and adequate.

STORAGE REQUIREMENTS

Store at Controlled Room Temperature between 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature]. Avoid exposure to heat. Keep tightly closed. Keep this out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

PRESENTATION

Tuss-one Syrup is alcohol-free, and raspberry flavored. It is available in 100ml pet bottles and 60ml pet bottles. Dispense in a tight, light-resistant container and with a Aluminium PP cap closure.