

norel[®] DM



Antihistamine-Nasal Decongestant-Cough Suppressant

Alcohol Free Sugar Free Dye Free

This product information is intended for physicians and is the entire product information.
NO OTHER INFORMATION, WHETHER ORAL OR IN WRITING, SHOULD BE RELIED UPON!

DESCRIPTION: Each teaspoonful (5 mL) contains:

Dextromethorphan Hydrobromide 15 mg
Chlorpheniramine Maleate..... 4 mg
Phenylephrine Hydrochloride..... 10 mg

The inactive ingredients present are glycerin, grape flavor, propylene glycol, sorbitol, and water.

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. Chlorpheniramine maleate is an antihistamine with anticholinergic and sedative effects. Antihistamines 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:

Norel DM is indicated for the temporary relief of allergy induced nasal congestion, runny nose, sneezing, and cough caused from inhalation of airborne antigens and other irritants.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients. Because of its drying effect on lower respiratory secretions, this product 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.

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, indomethacin or with beta-blockers and methyl dopa. If a hypertensive crisis occurs, this product 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 overdose may cause hallucinations, convulsions, and death.

PRECAUTION:

General: Use with caution in patients with a history of bronchial asthma, gastrointestinal obstruction, or urinary bladder neck obstruction. Because of its sympathomimetic component, this product should be used cautiously 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.

Drug Interactions: Antihistamines have additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, anti-anxiety 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 may produce an additive elevation of blood pressure. MAO inhibitors may prolong the anticholinergic effects of antihistamines. (See WARNINGS)

Carcinogenesis, Mutagenesis, Impairment of Fertility: Animal studies to assess the carcinogenic and mutagenic potential, or the effect on fertility have not been performed.

Usage in Pregnancy: Teratogenic Effects: Pregnancy Category C. Animal reproduction studies have not been conducted with this product. It is also 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: It is also not known whether this product is excreted in human milk. 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.

ADVERSE REACTIONS:

The most frequent adverse reactions 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. Respiratory System: Tightness of chest and wheezing, shortness of breath.

Hematologic System: Hemolytic anemia, thrombocytopenia, agranulocytosis.

OVERDOSAGE:

Signs and symptoms: Dextromethorphan in toxic doses will cause drowsiness, ataxia, nystagmus, opisthotonos, and convulsive seizures. Symptoms of overdosage with phenylephrine include hypertension, headache, convulsions, cerebral hemorrhage, and vomiting. Effects of antihistamine overdosage 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, tracheostomy 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 overdosage 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 12 years of age and over: One teaspoonful every four hours as needed. Children 6 to under 12 years of age: One-half teaspoonful every four hours as needed. Children under 6 years of age: As directed by physician. Do not exceed six doses in a 24-hour period.

HOW SUPPLIED:

NOREL DM™ is supplied in bottles of 1 pint (16 fluid ounces) - NDC #52747-410-90 and in bottles of 20 mL - NDC #52747-410-01

STORAGE: Store at controlled room temperature: 15°-30°C (59°-86°F).

PHARMACIST: Dispense in a tight, light-resistant container with a child resistant closure.

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. IN CASE OF ACCIDENTAL OVERDOSE, SEEK PROFESSIONAL ASSISTANCE OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

Rx Only

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Products designed with the patient in mind.™