Dimetane®-DX Cough Syrup

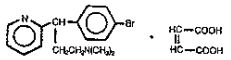
SUGAR-FREE

Rx only

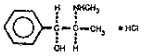
DESCRIPTION

Dimetane-DX Cough Syrup is a light-red syrup with a butterscotch flavor.
Each 5 mL (1 teaspoonful) contains:

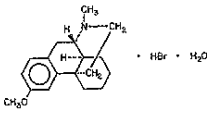
Brompheniramine Maleate, USP	2 mg
Pseudoephedrine Hydrochloride, USP	30 mg
Dextromethorphan Hydrobromide, USP	10 mg



Brompheniramine Maleate, USP
2-Pyridinepropanamine, γ-(4-bromophenyl)-N,N-dimethyl-,(Z)-butenedioate (1:1).



Pseudoephedrine Hydrochloride, USP
Benzenemethanol, α-[1-(methylamino)ethyl]-,[S-(R*,R*)]-, hydrochloride.



Dextromethorphan Hydrobromide, USP
Morphinan, 3-methoxy-17-methyl-,(9α, 13α, 14α)-, hydrobromide, monohydrate.

Alcohol 0.95 percent
In a palatable, aromatic vehicle.
Inactive Ingredients: Citric Acid, FD&C Red 40, FD&C Yellow 6, Flavors, Glycerin, Saccharin Sodium, Sodium Benzoate, Sorbitol, Water.
Antihistamine/Nasal Decongestant/Antitussive syrup for oral administration.

CLINICAL PHARMACOLOGY

Brompheniramine maleate is a histamine antagonist, specifically an H_1-receptor-blocking agent belonging to the alkylamine class of antihistamines. Antihistamines appear to compete with histamine for receptor sites on effector cells. Brompheniramine also has anticholinergic (drying) and sedative effects. Among the antihistaminic effects, it antagonizes the allergic response (vasodilatation, increased vascular permeability, increased mucus secretion) of nasal tissue.
Brompheniramine is well absorbed from the gastrointestinal tract, with peak plasma concentration after single, oral dose of 4 mg reached in 5 hours; urinary excretion is the major route of elimination, mostly as products of biodegradation; the liver is assumed to be the main site of metabolic transformation.
Pseudoephedrine acts on sympathetic nerve endings and also on smooth muscle, making it useful as a nasal decongestant. The nasal decongestant effect is mediated by the action of pseudoephedrine on α-sympathetic receptors, producing vasoconstriction of the dilated nasal arterioles. Following oral administration, effects are noted within 30 minutes with peak activity occurring at approximately one hour.
Dextromethorphan 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.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients. Do not use in the newborn, in premature infants, in nursing mothers, or in patients with severe hypertension or severe coronary artery disease. Do not use dextromethorphan in patients receiving monoamine oxidase (MAO) inhibitors (see **PRECAUTIONS - Drug Interactions**).
Antihistamines should not be used to treat lower respiratory tract conditions including asthma.

WARNINGS

Especially in infants and small children, antihistamines in overdosage may cause hallucinations, convulsions, and death.
Antihistamines may diminish mental alertness. In the young child, they may produce excitation.

PRECAUTIONS

General

Because of its antihistamine component, Dimetane-DX Cough Syrup should be used with caution in patients with a history of bronchial asthma, narrow angle glaucoma, gastrointestinal obstruction, or urinary bladder neck obstruction. Because of its sympathomimetic component, Dimetane-DX Cough Syrup should be used with caution in patients with diabetes, hypertension, heart disease, or thyroid disease.

Information for Patients

Patients should be warned about engaging in activities requiring mental alertness, such as driving a car or operating dangerous machinery.

Drug Interactions

Monoamine oxidase (MAO) inhibitors—Hyperpyrexia, hypotension, and death have been reported coincident with the co-administration of MAO inhibitors and products containing dextromethorphan. In addition, MAO inhibitors prolong and intensify the antichotinergic (drying) effects of antihistamines and may enhance the effect of pseudoephedrine. Concomitant administration of Dimetane-DX and MAO inhibitors should be avoided (see **CONTRAINDICATIONS**).
Central nervous system (CNS) depressants—Antihistamines have additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, antianxiety agents, etc.).
Antihypertensive drugs—Sympathomimetics may reduce the effects of antihypertensive drugs.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies of Dimetane-DX Cough Syrup to assess the carcinogenic and mutagenic potential or the effect on fertility have not been performed.

Pregnancy Category C

Teratogenic Effects

Animal reproduction studies have not been conducted with Dimetane-DX Cough Syrup. It is also not known whether Dimetane-DX Cough Syrup can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dimetane-DX Cough Syrup should be given to a pregnant woman only if clearly needed.
Reproduction studies of brompheniramine maleate (a component of Dimetane-DX Cough Syrup) in rats and mice at doses up to 16 times the maximum human dose have revealed no evidence of impaired fertility or harm to the fetus.

Nursing Mothers

Because of the higher risk of intolerance of antihistamines in small infants generally, and in newborns and prematures in particular, Dimetane-DX Cough Syrup is contraindicated in nursing mothers.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 6 months have not been established (see **DOSAGE AND ADMINISTRATION**).

Geriatric Use

Clinical studies of Dimetane-DX did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. However, antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients. The elderly are also more likely to experience adverse reactions to sympathomimetics.
In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

The most frequent adverse reactions to Dimetane-DX Cough Syrup are: sedation; dryness of mouth, nose and throat; thickening of bronchial secretions; dizziness. Other adverse reactions may include:

Dermatologic

Urticaria, drug rash, photosensitivity, pruritus.

Cardiovascular System

Hypotension, hypertension, cardiac arrhythmias, palpitation.

CNS

Disturbed coordination, tremor, irritability, insomnia, visual disturbances, weakness, nervousness, convulsions, headache, euphoria, and dysphoria.

G.U. System

Urinary frequency, difficult urination.

G.I. System

Epigastric discomfort, anorexia, nausea, vomiting, diarrhea, constipation.

Respiratory System

Tightness of chest and wheezing, shortness of breath.

Hematologic System

Hemolytic anemia, thrombocytopenia, agranulocytosis.

OVERDOSAGE

Signs and Symptoms

Central nervous system effects from overdosage of brompheniramine may vary from depression to stimulation, especially in children. Anticholinergic effects may be noted. Toxic doses of pseudoephedrine may result in CNS stimulation, tachycardia, hypertension, and cardiac arrhythmias; signs of CNS depression may occasionally be seen. Dextromethorphan in toxic doses will cause drowsiness, ataxia, nystagmus, opisthotonos, and convulsive seizures.

Toxic Doses

Data suggest that individuals may respond in an unexpected manner to apparently small amounts of a particular drug. A 2½-year-old child survived the ingestion of 21 mg/kg of dextromethorphan exhibiting only ataxia, drowsiness, and fever, but seizures have been reported in 2 children following the ingestion of 13-17 mg/kg. Another 2½-year-old child survived a dose of 300-900 mg of brompheniramine. The toxic dose of pseudoephedrine should be less than that of ephedrine, which is estimated to be 50 mg/kg.

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 overdose 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 pediatric patients 12 years of age and over: 2 teaspoonfuls every 4 hours. Children 6 to under 12 years: 1 teaspoonful every 4 hours. Children 2 to under 6 years: 1/2 teaspoonful every 4 hours. Infants 6 months to under 2 years: Dosage to be established by physician.
Do not exceed 6 doses during a 24-hour period.

HOW SUPPLIED

Dimetane®-DX Cough Syrup is a light-red syrup containing in each 5 mL (1 teaspoonful) brompheniramine maleate 2 mg, pseudoephedrine hydrochloride 30 mg and dextromethorphan hydrobromide 10 mg, available in pints (NDC 0031-1836-25).
Store at controlled room temperature, between 20°C and 25°C (68°F and 77°F).
Dispense in tight, light-resistant container.

A·H·ROBINS

Pharmaceutical Division
A.H. Robins Company
Richmond, VA 23220

CI 4691-2

Revised May 31, 2001