SILDEC PE DM- sildec pe dm syrup
Rebel Distributors Corp

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

CHLORPHENIRAMINE / PHENYLEPHRINE/ DEXTROMETHORPHAN Syrup (CPM/PE/DM Syrup)

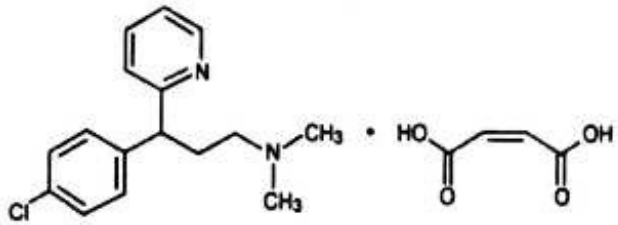
DESCRIPTION

CPM/PE/DM Syrup is a sugar-free, alcohol-free, grape flavored syrup for oral administration for adults and for pediatric patients 2 years and older.

Each teaspoonful (5 mL) contains:
Chlorpheniramine maleate ……. 4.0 mg
Phenylephrine hydrochloride ……. 12.5 mg
Dextromethorphan hydrobromide …….. 15.0 mg

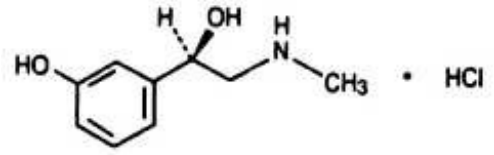
Inactive ingredients: Citric acid, D&C Red No. 33, FD&C Blue No. 1, flavor, glycerin, purified water, sodium benzoate, sodium saccharin, and sorbitol. May contain sodium citrate.

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



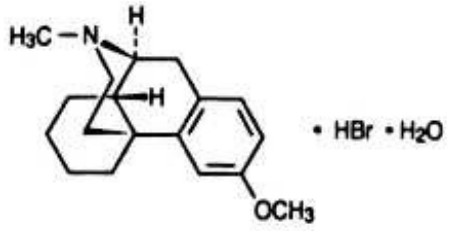
$C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$ M.W. 390.86

Phenylephrine hydrochloride is a mydriatic and a decongestant with the chemical name: (-)-m-Hydroxy-α-[(methylamino)methyl]benzyl alcohol hydrochloride. Its chemical structure is as follows:



$C_9H_{13}NO_2 \cdot HCl$ M.W. 203.67

Dextromethorphan hydrobromide is an antitussive with the chemical name 3-Methoxy-17-methyl-9α, 13α, 14α - morphinan hydrobromide monohydrate. Its structure is as follows:



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

CLINICAL PHARMACOLOGY

Antihistaminic, decongestant and antitussive actions.

Chlorpheniramine maleate possesses H_1 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.

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 excreted in the urine.

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 activity. Dextromethorphan is rapidly metabolized with trace amounts of the parent compound in blood and urine. About one-half of the administered dose is excreted in the urine as conjugated metabolites.

INDICATIONS AND 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.

Sympathomimetic 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) or for 2 weeks after stopping the MAOI drug.

WARNINGS

Do not exceed recommended dosage.

Sympathomimetic amines should be used judiciously and sparingly in patients with hypertension, diabetes, ischemic heart disease, hyperthyroidism, increased intraocular pressure or prostatic hypertrophy (See CONTRAINDICATIONS). Sympathomimetic amines may produce CNS stimulation with convulsions or cardiovascular collapse with accompanying hypotension. The elderly (60 years and older) are more likely to exhibit adverse reactions. Antihistamines may cause excitability, especially in children. 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 atopic children.

PRECAUTIONS

General: Before prescribing medication to suppress or modify cough, identify and provide therapy for the underlying cause of the cough and take caution that modification of cough does not increase the risk of clinical or physiologic complications. Dextromethorphan should be used with caution in sedated or debilitated patients and in patients confined to supine positions. Use with caution in patients with hypertension, heart disease, asthma, hyperthyroidism, increased intraocular pressure, diabetes mellitus

and prostatic hypertrophy.

Information for Patients: Avoid alcohol and other CNS depressants while taking this product. Patients sensitive to antihistamines may experience moderate to severe drowsiness. Patients sensitive to sympathomimetic amines may notice mild CNS stimulation. Antihistamines may impair mental and physical abilities required for the 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. MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines. Sympathomimetic amines may reduce the antihypertensive effects of reserpine, veratrum alkaloids, methyldopa and mecamylamines. Effects of sympathomimetics are increased with MAO inhibitors and beta-adrenergic blockers. The cough-suppressant action of dextromethorphan and narcotic antitussives are additive. Dextromethorphan is contraindicated with monoamine oxidase inhibitors (MAOI). (See **CONTRAINDICATIONS** section.)

Use in Pregnancy: Pregnancy Category C. Animal reproduction studies have not been conducted with CPM/PE/DM Syrup. It is not known whether these products can cause fetal harm when administered to a pregnant woman or affect reproduction capacity. Give to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether the drugs in CPM/PE/DM Syrup are excreted in human milk. Since many drugs are excreted in human milk and because of the potential for serious side effects in nursing infants, a decision should be made whether to discontinue nursing or discontinue the use of these products, taking into account the importance of the drug to the mother.

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. Urinary retention may occur in patients with prostatic hypertrophy. Sympathomimetic amines may cause convulsions, CNS stimulation, cardiac arrhythmia, respiratory difficulties, increased heart rate or blood pressure, hallucinations, tremors, nervousness, insomnia, pallor and dysuria. Dextromethorphan may cause drowsiness, dizziness and GI disturbance.

OVERDOSAGE

No information is available as to specific results of an overdose of CPM/PE/DM Syrup. The signs, symptoms and treatments described below are those of H_1 antihistamine, ephedrine, and dextromethorphan overdose.

Symptoms: Should antihistamine effects predominate, central action constitutes the greatest danger. In the small child, predominant symptoms are excitation, hallucination, ataxia, incoordination, tremors, flushed face and fever. Convulsions, fixed and dilated pupils, coma and death may occur in severe cases. In the adult, fever and flushing are uncommon; excitement leading to convulsions and postictal depression is often preceded by drowsiness and coma. Respiration is usually not seriously depressed; blood pressure is usually stable.

Should sympathomimetic symptoms predominate, central effects include restlessness, dizziness, tremor, hyperactive reflexes, talkativeness, irritability and insomnia. Cardiovascular and renal effects include difficulty in micturition, 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.

Dextromethorphan may cause respiratory depression with a large overdose.

Treatment: (a) Evacuate stomach as condition warrants. Activated charcoal may be useful. (b) Maintain a nonstimulating environment. (c) Monitor cardiovascular status. (d) Do not give stimulants. (e) Reduce

fever with cool sponging. (f) Treat respiratory depression with naloxone if dextromethorphan toxicity is suspected. (g) Use sedatives or anticonvulsants to control CNS excitation and convulsions. (h) Physostigmine may reverse anticholinergic symptoms. (i) Ammonium chloride may acidify the urine to increase urinary excretion of phenylephrine. (j) Further care is symptomatic and supportive.

DOSAGE AND ADMINISTRATION

CHLORPHENIRAMINE / PHENYLEPHRINE/ DEXTROMETHORPHAN Syrup (CPM/PE/DM Syrup) Adults and Children 12 years of age and older: 1 teaspoonful (5 mL) every 4 to 6 hours, not to exceed 6 teaspoonfuls 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 teaspoonfuls 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 teaspoonfuls 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.

HOW SUPPLIED

CHLORPHENIRAMINE / PHENYLEPHRINE/ DEXTROMETHORPHAN Syrup (CPM/PE/DM Syrup) CPM/PE/DM Syrup is sugar-free, alcohol-free, and grape flavored.

It is available in bottles of 16 fluid ounce (473 mL) bottles - **NDC 21695-900-16**.

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

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 AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

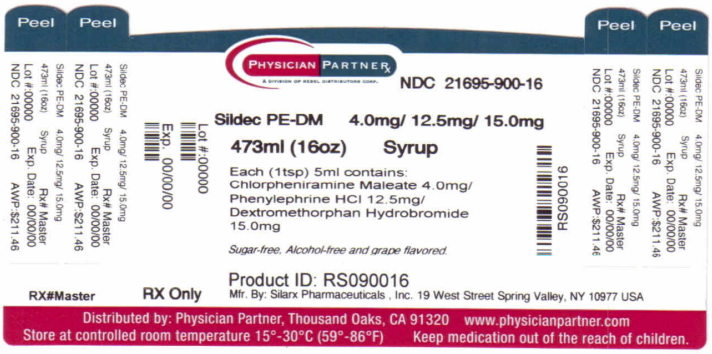
Manufactured by:
Silarx Pharmaceuticals, Inc.
Spring Valley, NY 10977
USA

Repackaged by:

Rebel Distributors Corp

Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL



SILDEC PE DM

sildec pe dm syrup

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:21695-900(NDC:54838-544)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	4 mg in 5 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	12.5 mg in 5 mL
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	15 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	GRAPE (grape flavor)	**Imprint Code**	

Contains		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-900-16	473 mL in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		03/31/2010	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 4/2011 Rebel Distributors Corp