Dextromethorphan Hydrobromide, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Syrup

EASCOF-D

SUGAR FREE

COMPOSITION:
Each 5ml contains:
Dextromethorphan Hydrobromide BP ..... 10 mg
Phenylephrine Hydrochloride BP ..... 5 mg
Chlorpheniramine Maleate BP ..... 2 mg
Colour: Sunset Yellow

Preservative Content: Sodium Benzoate

PHARMACEUTICAL FORM:
Oral Solution

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

DOSAGE AND METHOD OF ADMINISTRATION:
Chlorpheniramine / Phenylephrine/ Dextromethorphan 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 us e in children under 2 years of age.

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.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
WARNING: Sympathomimetic amines should be used in patients with hypertension, diabetes, ischemic heart disease, hyperthyroidism, increased intraocular pressure or prostatic hypertrophy. Sympathomimetic amines may produce CNS stimulation with convulsions or cardiovascular collapse with accompanying hypotension. 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. Use with caution in patients with hypertension, heart disease, asthma, hyperthyroidism, increased intraocular pressure, diabetes mellitus 1 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.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
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. Dextromethorphan is contraindicated with monoamine oxidase inhibitors (MAOI).

FERTILITY, PREGNANCY AND LACTATION:
Us e in Pregnancy:
Pregnancy Category C: It is not known whether these products can cause fetal harm when administered to a pregnant woman or affect reproduction capacity.
Nursing Mothers: It is not known whether the drugs in CHLORPHENIRAMINE / PHENYLEPHRINE/ DEXTROMETHORPHAN 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.

EFFECT ON ABILITY TO DRIVE AND USE MACHINES
Antihistamines may impair mental and physical abilities required for the performance of potentially hazardous tasks such as driving a vehicle or operating machinery.

UNDESIRABLE EFFECTS:
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.

OVERDOSE:
No information is available as to specific results of an overdose of CHLORPHENIRAMINE / PHENYLEPHRINE/ DEXTROMETHORPHAN Syrup.

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.
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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 1 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.

CLINICAL PHARMACOLOGY
Antihistaminic, decongestant and antitussive actions.
Chlorpheniramine maleate possesses H 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.

STORAGE:
Store below 30°C. Protect from light.
Keep out of reach of children.

PRESENTATION :
100 ml Orange Transparent Round Pet Bottle

SHELF LIFE: 24 months

Made in India by:
CACHET PHARMACEUTICALS PVT. LTD.
Village - Thana, Baddi, Distt. - Solan, Himachal Pradesh - 173 205.
H.O.: 415, Shah Nahar, Worli, Mumbai - 400 018. INDIA.
www.cachetindia.com

APPROVAL BOX

Black

Product Name : Eascof D Syrup

Packing Details :

Packing Style : Insert
Dimensions : 100 X 200 mm
Artwork Code :
Specification : 50-60 gsm White mapltho paper
Colours : Black

Manufacturing Details :

Location : Baddi
Mfg. Lic. No. : MNB/05/267
Barcode No. : NA
Category : Export
Country : Mauritius

Artwork Details :

Designed by : Sachin
Developed on : 27/08/2019
Modified Date : 28/12/2020
Revision No. :
Reason :
Recommended by : Snehal/ Asma