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Cosome- E Cough Syrup Leaflet		
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Martin Dow

Cosome®-E

کوسوم®-ای

Cough Syrup

(Ammonium Chloride + Diphenhydramine Hydrochloride + Aminophylline)

کھانسی کا شربت

1. COMPOSITION

Each 5 ml contains:

Ammonium Chloride USP ..... 30 mg
Diphenhydramine Hydrochloride USP ..... 8 mg
Aminophylline USP ..... 32 mg

2. DESCRIPTION

Cosome E Syrup is the combination of Ammonium Hydrochloride, Diphenhydramine HCl and Aminophylline.

Diphenhydramine is an antihistamine. It blocks the effects of the naturally occurring chemical histamine in the body. It is used to treat sneezing; runny nose; itching, watery eyes; hives; rashes; itching; and other symptoms of allergies and the common cold. Also used to suppress coughs, to treat motion sickness, to induce sleep, and to treat mild forms of Parkinson's disease. It may also be used for the treatment of extrapyramidal side effects of typical antipsychotics.

Aminophylline is a bronchodilator, it relaxes muscles in your lungs and chest to allow more air in, decreases the sensitivity of your lungs to allergens and other substances that cause inflammation, and increases the contractions of your diaphragm to draw more air into the lungs. Used to treat the symptoms of asthma, bronchitis, and emphysema.

Ammonium chloride is as an expectorant. An expectorant is a drug that stimulates, depresses or modifies the secretions of the bronchial mucus membrane and promote its expulsion. It is considered as a safe and effective medicine for the remedy of cough.

3. THERAPEUTIC INDICATIONS

Productive cough, smokers cough, cough associated with asthma and cough due to bronchitis and other respiratory diseases. Also, for all uncomplicated productive coughs especially associated with respiratory system and nasal allergy.

Diphenhydramine is frequently used when an allergic reaction requires fast, effective reversal of the often-dangerous effects of a massive histamine release.

Aminophylline is indicated for the treatment of reversible bronchospasm associated with chronic bronchitis, emphysema, bronchial asthma and chronic obstructive pulmonary disease. It may also be used for paroxysmal dyspnea associated with left heart failure.

4. POSOLGY AND METHOD OF ADMINISTRATION

- Children 2 to 6 years: ¼ to ½ of a 5ml teaspoon, every 4 to 6 hours as indicated.
- Children 6 to 12 years: ½ to 1 of a 5 ml teaspoon full, every 4 to 6 hours as indicated.
- 12 years and above: 1 to 2 of a 5 ml teaspoon full, every 4 to 6 hours as indicated.

5. CONTRAINDICATIONS

- Children under the age of 2 years
- Cosome E should not be given to patients with stenosing peptic ulcer ,active peptic ulcers, pyloroduodenal obstruction, acute gastritis, acute myocardial infarction, severe hypertension, coronary artery disease, bronchiolitis, acute pulmonary edema, epilepsy and tachyarrhythmia.
- It should not be used in patients with hypersensitivity to its components.
- Aminophylline is contraindicated in patients hypersensitive to xanthines ethylenediamine or any of the excipients and in patients with coronary artery disease where myocardial stimulation might prove harmful.
- Because of its diphenhydramine component, use caution in asthmatic patients.

6. SPECIAL WARNINGS AND PRECAUTIONS FOR USE

- Some patients particularly children may be unusually sensitive to Aminophylline.
- Cosome E should be used with care in conditions such as, angle-closure glaucoma, urinary retention, or prostatic hyperplasia, myasthenia gravis, epilepsy or seizure disorders, asthma, bronchitis and chronic obstructive pulmonary disease (COPD), moderate to severe hepatic impairment and moderate to severe renal impairment, hypothyroidism, sepsis with multiorgan failure, shock, cessation of smoking, severe cardiac disease, coronary artery disease and congestive heart failure, hypertension, history of peptic ulcer or thyrotoxicosis.
- Patients should be cautioned against operating motor vehicles or machinery while taking Cosome E as it produces sedation and dizziness.
- Tolerance may develop with continuous use. Seek medical advice if sleeplessness persists, as insomnia may be a symptom of serious underlying medical illness.
- Avoid use of other antihistamine-containing preparations, including topical antihistamines and cough and cold medicines.
- Avoid use in elderly patients with confusion as elderly are more likely to experience adverse effects.
- This medication should not be used continuously for more than 2 weeks without consulting a doctor.
- Cosome E may increase the effects of alcohol; therefore, alcohol should be avoided.

6. ADVERSE EFFECTS

Psychomotor skills impairment, ataxia, sedation, drowsiness, disturbance in attention, unsteadiness, dizziness, headache, short term memory loss, difficulty concentrating, blurred vision, photophobia, mydriasis, sinus tachycardia, thickening of bronchial secretions, tachypnea, dry mouth, gastrointestinal disturbance including gastroesophageal reflux, nausea, vomiting, hematemesis, diarrhea, constipation, urinary difficulty, urinary retention, polyuria, albuminuria, fatigue.

7. DRUG INTERACTIONS

Cosome E should not be used with other drugs having anticholinergic properties.

Diphenhydramine

- The diphenhydramine component may cause drowsiness and may potentiate the effects sedatives, hypnotics, tranquilizers and alcohol.
- Diphenhydramine can inhibit the oxidative metabolism of some drugs.
- Diphenhydramine may enhance the effects of ephedrine.
- Diphenhydramine has potential for interaction with drugs which are primarily metabolized by CYP2D6, such as metoprolol and venlafaxine as it is an inhibitor of it.
- Diphenhydramine may mask the response of the skin to allergenic skin tests and the ototoxic symptoms associated with certain antibiotics.

Aminophylline

- It may interact with other sympathomimetic drugs and mono-amine oxidase inhibitors to produce enhanced toxicity. Cosome E should be avoided within the 14 days after the suspension of such therapy.
- **The following drugs may decrease Aminophylline clearance resulting in increased serum levels and the potential for increased toxicity:** Alcohol, high dose allopurinol, beta-blockers, cimetidine, estrogen containing oral contraceptives, diltiazem, disulfuram, recombinant alpha-interferon, methotrexate, mexiletine, propranolol, tacrine, thiabendazole, thyroid hormones, ticlopidine, verapamil, and macrolide antibiotics and quinolones.
- **The following drugs may increase the clearance of Aminophylline, and thereby decrease serum concentrations, possibly resulting in sub therapeutic dosing:** Aminoglutethimide barbiturates including phenobarbitone and primidone, carbamazepine, isoprenaline, phenytoin, rifampicin, St John's wort, sulfinpyrazone, thioamines and tobacco and marijuana smoking.
- Aminophylline antagonizes the cardiovascular effects of adenosine. It inverts the sedative effect of benzodiazepines and antagonizes the bronchospasmodic effect of beta-blockers, the symptoms such as: nausea, anxiety, insomnia, are potentiated by ephedrine. Together with halothane can provoke arrhythmia. It antagonizes the blocking effect of non-depolarizing neuromuscular blockers. Together with ketamine it decreases the seizure threshold.

8. FRTILITY PREGNANCY AND LACTATION

Pregnancy: Aminophylline inhibits slightly the uterine contractions. Use of sedating antihistamines during the third trimester may result in reactions in the newborn or premature neonates. This drug is not recommended during pregnancy.

Lactation: Aminophylline provokes anxiety, accelerated heart activity and vomiting in the new-born. Use not recommended.

9. CLINICAL PHARMACOLOGY

Diphenhydramine hydrochloride: It is a member of the ethanolamine class of anti-histaminergic agents. Diphenhydramine works by blocking the effect of histamine at H1 receptor sites. This results in effects such as the reduction of smooth muscle contraction, making diphenhydramine a popular choice for treatment of the symptoms of allergic rhinitis, hives, motion sickness, and insect bites and stings.

Aminophylline: Aminophylline is a 2:1 complex of theophylline and ethylenediamine. Aminophylline has greater water solubility than theophylline. In biological fluids Aminophylline dissociates to theophylline hence the pharmacological effects of Aminophylline are those of theophylline. Theophylline is a xanthine derivative with the

main pharmacological action of direct relaxation of bronchial smooth muscle, relieving bronchospasm.

Ammonium Chloride: Ammonium chloride, (NH4) Cl is a systemic acidifying agent that has been used as a diuretic and an expectorant.

10. OVERDOSAGE

Diphenhydramine overdose may cause convulsions, coma, mydriasis, fever, flushing, drowsiness, dizziness, diarrhea, abdominal pain, hematemesis, agitation, tremor, dystonic reactions, and hallucinations. Some patients have an allergic reaction to diphenhydramine in the form of hives. Overdoses should be treated with gastric lavage and aspiration. Diazepam can be given for management of seizures and physostigmine for diphenhydramine induced anticholinergic effects.

Presentation:

Cosome®-E Cough Syrup: Available in 120 ml glass bottle.

Store below 30 °C.

Protect from light and heat.

Keep all medicines out of the reach of children.

To be sold on the prescription of a registered medical practitioner only.

۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

روشنی اور گرمی سے محفوظ رکھیں۔

تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ میڈیکل پریکٹیشنر کے نسخے پر فروخت کے لئے۔

Manufactured by:

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7, Jail Road, Quetta, Pakistan.

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