SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Product Name: EASCOF-D

(**Dextromethorphan Hydrobromide, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Syrup)**

1.2 Strength:

Dextromethorphan Hydrobromide BP…….10 mg

Phenylephrine Hydrochloride BP……..5 mg

Chlorpheniramine Maleate BP…….2 mg

1.3 Pharmaceutical Dosage Form: Oral Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:
Dextromethorphan Hydrobromide BP…….10 mg
Phenylephrine Hydrochloride BP……..5 mg
Chlorpheniramine Maleate BP…….2 mg
Colour: Sunset Yellow
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Visual description of finished product:

Orange colour clear liquid having pleasant flavor.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications and Usage

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

4.2. Posology 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.

4.3. 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 notbe used in patients receiving a monoamine oxidase inhibitor (MAOI) or for 2 weeks after stopping the MAOI drug.

4.4. Special Warning and Precautions for use

WARNINGS

Sympathomimetic amines should be used judiciously and sparingly 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 theunderlying cause of the cough and take caution that modification of cough does not increase the risk ofclinical 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. Patientssensitive to antihistamines may experience moderate to severe drowsiness. Patients sensitive tosympathomimetic amines may notice mild CNS stimulation. Antihistamines may impair mental andphysical abilities required for the performance of potentially hazardous tasks such as driving a vehicle oroperating machinery.

4.5 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).

4.6 Fertility, pregnancy and lactation

Use 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.

4.7. Effects 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.

4.8 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.

4.9 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.

Treatment: (a) Evacuate stomach as condition warrants. Activated charcoal may be useful. (b) Maintain a non-stimulating 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties Antihistaminic, decongestant and antitussive actions.

ATC CODE: Dextromethorphan HydrobromideN07XX59, Phenylephrine HydrochlorideR01BA53, Chlorpheniramine Maleate R06AB04.

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.

5.2 Pharmacokinetics:

Dextromethorphan suppresses the cough reflex by a direct action on the cough center in the medulla of the brain. Dextromethorphan shows high affinity binding to several regions of the brain, including the medullary cough center. This compound is an NMDA receptor antagonist and acts as a non-competitive channel blocker. It is one of the widely used antitussives and is also used to study the involvement of glutamate receptors in neurotoxicity.

Phenylephrine is an alpha-1 adrenergic agonist that raises blood pressure, dilates the pupils, and causes local vasoconstriction. Ophthalmic formulations of phenylephrine act for 3-8 hours while intravenous solutions have an effective half-life of 5 minutes and an elimination half-life of 2.5 hours. Patients taking ophthalmic formulations of phenylephrine should be counselled about the risk of arrhythmia, hypertension, and rebound miosis.

Chlorpheniramine has a serum half-life of approximately 20 hours in adults, and elimination from the body is primarily by metabolism to monodesmethyl and didesmethyl compounds. The half-life is increased in the presence of renal dysfunction and decreased in children.

5.3 Preclinical safety data

Non-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients (s)

Menthol
Sorbitol Solution 70% (NC)
Xanthan Gum
Sodium Benzoate
EDTA Sodium
Glycerine
Propylene Glycol
Sodium Chloride
Citric Acid Monohydrate
Neotame
Sucralose
Colour Sunset Yellow FCF
Flavour Mix Fruit (BB12) Blooming Buds
Flavour BTM

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years 24 Months

6.4 Special precautions for storage

Store in dry place, below 30^0C. Protect from Light. Keep out of the reach of Children.

6.5 Nature and contents of container

Primary Packing:100 ml Orange Trasparent Round Pet Bottle.

Secondary Packing:Carton Containing 100 ml Orange Trasparent Round Pet Bottle along with its pack insert.

6.6 Special precautions for disposal <and other handling>

Not Applicable.

7. MARKETING AUTHORISATION HOLDER

Cachet Pharmaceuticals Pvt. Ltd

415, Shah Nahar Industrial Estate,

Dr. E. Moses Road, Worli, Mumbai-400 018,

Maharashtra, India.

Phone No. Office +91-22-40829991

Email:-regulatory@cachetpharma.com

8. MARKETING AUTHORISATION NUMBER(S)

06938/08117 /NMR/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 31.03.2022

10. DATE OF REVISION OF THE TEXT

05.07.2023