SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

a) Product Name: Eascof Expectorant (Salbutamol Sulphate, Bromhexine hydrochloride, Guaifenesin, Menthol Syrup).

b) Strength of drug product:

Bromhexine Hydrochloride BP: 4 mg

Salbutamol Sulphate BP equivalent

to Salbutamol: : 2mg

Guaifenesin BP : 100 mg

Menthol BP : 1 mg

c) Pharmaceutical Dosage Form: Syrup for Oral use

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Each 10 ml contains:

Bromhexine Hydrochloride BP: 4 mg

Salbutamol Sulphate BP equivalent

to Salbutamol: : 2mg

Guaifenesin BP : 100 mg

Menthol BP : 1 mg

Colour- Sunset Yellow FCF

In flavoured syrupy base

3. PHARMACEUTICAL FORM

Syrup for Oral use

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Eascof Expectorant is indicated for clinical relief of cough associated with bronchitis, bronchial asthma, emphysema and other bronchopulmonary disorders where bronchospasm, mucous plugging and problems of expectoration co-exist.

4.2 Posology and method of administration

Adults:10- 20ml thrice daily (10ml)

Children: 6-12 yrs – 10ml thrice

Children: (under 6 yrs) -5-10 ml thrice daily

4.3 Contraindications

Hypersensitivity to the components of the formulation.

4.4 Special warnings and precautions for use

While treating cough as a symptom, it is important to make every effort to determine and treat appropriately the underlying cause, such as specific infection. Caution should be observed while prescribing EASCOF to patients with hypertension, cardiovascular disease (including arrhythmias, coronary insufficiency, uncontrolled diabetes mellitus & patients with hyperthyroidism, history of seizures or in patients who are unusually responsive to sympathomimetic amines.

Patients susceptible to hypokalemia should be monitored because transient early falls in serum potassium have been reported with beta agonists. Since, mucolytics, such as bromhexine may disrupt the gastric mucosal barriers, bromhexine should be used with care in patients with a history of peptic ulceration.

4.5 Interaction with other medicinal products and other forms of interaction

Sympathomimetic agents: Concomitant use of Eascof Expectorant with other oral sympathomimetic agents is not recommended.

Beta-receptor blocking agents and Salbutamol inhibit the effect of each other.

Monoamine oxidase inhibitors: Salbutamol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants since the action of Salbutamol on the vascular system may be potentiated.

Others

Eascof Expectorant should be used with caution in patients with diabetes mellitus, serious cardiovascular disorders, hypertension, hyperthyroidism and peptic ulcers.

4.6 Pregnancy and lactation

Pregnancy

This combination is not recommended for use in pregnancy.

Lactation

It is not known whether this combination is secreted in breast milk

Pediatric Use

Safety and effectiveness in children under the age of two years has not yet been adeequetly demonstrated.

4.7 Effects on ability to drive and use machines

4.8 Undesirable effects

These are generally mild and very rare. However, In isolated cases, fine finger tremors, palpitation gastrointestinal disturbances, fatigue, dry mouth and dysuria may be seen.

4.9 Overdose

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5. PHARMACOLOGICAL PROPERTIES

Salbutamol is a beta-adrenergic stimulant which has a highly selective action on the β2 - receptors in bronchial muscle resulting in 2 bronchodilations, and in therapeutic doses, little or no action on thevβ1cardiac receptors.

Bromhexine is a derivative of the alkaloid vasicine and possesses mucokinetic (improvement in mucus transport) and mucolytic properties. It depolymerises mucopolysaccharides directly as well as liberating lysosomal enzymes. It promotes the removal of tenacious secretions in the respiratory tract and reduces mucus stasis (arresting the secretion of mucus).

Guaifenesin, by increasing respiratory tract fluid, reduces the viscosity of tenacious secretions and acts as an expectorant. Another possible mechanism by which it acts is by increasing the water bonding in the sputum, thereby decreasing its viscosity and leading to an increase in mucokinesis. is effective in both productive and nonproductive coughs.

Menthol is having soothing action.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipient(s)

S. No.	Ingredients	Specification
1	Methyl Paraben	BP
2	Propyl Paraben	BP
3	Sodium Benzoate	BP
4	Sucrose	BP
5	Citric acid (Monohydrate)	BP
6	Colour Sunset Yellow FCF	IH
7	Sodium Chloride	BP
8	Propylene glycol	BP
9	Flavour Strawberry ID 26236	IH
10	Saccharin Sodium	BP
11	Purified water	BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 25°C. Protect from light.

Keep out of reach of Children. Shake well before use.

6.5 Nature and contents of container

100 ml in Orange coloured Pet Bottle sealed with 25 mm EPE WAD Cap.

6.6 Special precautions for disposal and other handling

Not Applicable

7. Marketing authorization holder

Cachet Pharmaceuticals Pvt. Ltd

415, Shah Nahar Industrial Estate,

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

Maharashtra, India.

Manufacturer's Name and Address:

Cachet Pharmaceuticals Pvt. Ltd

Village-Thana , Baddi, Dist-Solan ,

Himachal Pradesh – 173 205

8. Marketing authorization number(s)

Not Applicable

9. Date of first authorization/renewal of the authorization

Not Applicable

10. Date of revision of the text

Not Applicable