SUMMARY OF PRODUCT CHARACTERISTICS COSCOF-C LINCTUS

1. Name of the Medicinal Product

1.1 Proprietary Name

Coscof-C Linctus

1.2 Strength

Each 5mL contains: Chlorphenamine Maleate BP 2mg Sodium Citrate BP 44mg Pseudoephedrine HCl BP 30mg Codeine Phosphate BP 6mg

2. Qualitative and Quantitative Composition

Each 5mL contains: Chlorphenamine Maleate BP 2mg Sodium Citrate BP 44mg Pseudoephedrine HCl BP 30mg Codeine Phosphate BP 6mg

For full list of Excipients, see section 6.1

3. Pharmaceutical Form

Linctus

Product description

Caramel black coloured viscous liquid with a characteristic odour

4. Clinical Particulars

4.1 Therapeutic Indications

COSCOF®-C is a cough suppressant used in the symptomatic relief of unproductive cough associated with colds. The combined antihistamine effect of Chlorphenamine Maleate and bronchial dilator Pseudoephedrine Hydrochloride relieve irritation and congestion. The antitussive effect of Codeine Phosphate helps relief the discomfort or nuisance of frequent unproductive cough. COSCOF®-C is useful in both children and adults as a cough suppressant in unproductive cough.

4.2 Posology and Method of administration

Posology

Adults and children over 12 years: Two 5mL spoonful's (10mL) three to four times daily. Children 6 to 12 years: One 5mL spoonful three to four times daily. Children 2 to 6 years: Half 5mL spoonful (2.5mL) four times daily.

Method of Administration

Adults and children over 12 years: Two 5mL spoonful's (10mL) three to four times daily. Children 6 to 12 years: One 5mL spoonful three to four times daily. Children 2 to 6 years: Half 5mL spoonful (2.5mL) four times daily

4.3 Contraindication

The drug should be avoided in patients who are known to be allergic to any one of the components of the mixture. The preparation may cause drowsiness or in some cases excitability.

4.4 Special warnings and precautions for use

It should not be given to patients who have high blood pressure, organic heart disease, thyroid disease, diabetes mellitus, glaucoma and those who are on prescription drugs for depression.

4.5 Interaction with other medicinal products and other forms of interaction

Not known

4.6 Fertility, Pregnancy and lactation

Fertility

No evidence of associated effects on fertility

Pregnancy

Avoid use during pregnancy unless deemed by physician, particularly during first trimester

Lactation

Codeine should not be used during breastfeeding due to potential potential risks to the infant

4.7 Effects on ability to drive and use machines

Drowsiness due to antihistamine components which may interfere with alertness

4.8 Undesirable effects

- Drowsiness
- Excitability

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority pharmacovigilance reporting channels.

4.9 Overdose

Acute overdose does not result in any serious signs and symptoms unless massive amounts have been ingested. In such a situation the signs and symptoms include nausea, vomiting, visual disturbances, CNS disturbances, dizziness, tachycardia, mild hypertension, urinary retention. Symptoms appear within 4-8 hours and are usually transient, and are treated with supportive therapy maintenance of airway, oxygenation, hydration and circulatory management

5 Pharmacological Properties

5.1 Pharmacodynamic Properties

Chlorphenamine Maleate is a histamine H1-receptor antagonist. It is a common ingredient of cough and cold preparations because of its antihistamine effects. Sodium Citrate has humectant properties and play a role in the maintenance of pH. Pseudoephedrine Hydrochloride is a direct and indirect-acting sympathomimetic. It is a stereoisomer of ephedrine and has a similar action, but has been stated to have less pressor activity and fewer CNS effects.

Pseudoephedrine and its salts are given by mouth for the symptomatic relief of nasal congestion. They are commonly combined with other ingredients in preparations intended for the relief of cough and cold symptoms. Its main clinical use is a nasal decongestant and may be used alone or in combination with other agents for the relief of cold symptoms.

Codeine Phosphate is an antitussive used in the form of linctus's for relief of cough.

5.2 Pharmacokinetic Properties

Chlorphenamine Maleate is absorbed relatively slowly from the gastro-intestinal tract, peak plasma concentrations occurring about 2.5 to 6 hours after 3 administration by mouth. Bioavailability is low, values of 25 to 50% having been reported. Chlorphenamine appears to undergo considerable first-pass metabolism. About 70% of Chlorphenamine in the circulation is bound to plasma proteins. There is wide inter-individual variation in the pharmacokinetics of Chlorphenamine; values ranging from 2 to 43 hours have been reported for the half-life. Chlorphenamine is widely distributed in the body, including passage into CNS. Chlorphenamine Maleate is extensively metabolised. Unchanged drug and metabolites are excreted primarily in the urine. Only trace amounts have been found in the faeces. Sodium Citrate is metabolised, after absorption, to bicarbonate. Pseudoephedrine is readily and completely absorbed from the gastro-intestinal tract. It is resistant to metabolism by monoamine oxidase and is largely excreted unchanged in the urine, together with small amounts of metabolites produced by hepatic metabolism. It has a
half-life of about 5 to 8 hours; elimination is enhanced and half-life accordingly shorter in acid urine. Small amounts are distributed into breast milk. Codeine and its salts are absorbed from the gastro-intestinal tract. Ingestion of Codeine Phosphate produces peak plasma-codeine concentrations in about one hour.
Codeine is metabolised by O- and N- demethylation in the liver to morphine, norcodeine, and other metabolites including normorphine and hydrocodone.

Codeine and its metabolites are excreted almost entirely by the kidney, mainly as conjugates with glucuronic acid. The plasma half-life has been reported to be between 3 and 4 hours after administration by mouth**.**

6 Pharmaceutical Particulars

6.1 List of Excipients

- Potassium sorbate BP
- Sodium Benzoate BP
- Sucrose BP
- Liquid Glucose NF
- Sorbitol Solution 70% BP
- Saccharin Sodium BP
- Carmellose sodium BP

- Xanthan gum BP
- Citric Acid Anhydrous BP
- Gum acacia
- Rectified spirit BP
- Sodium hydroxide BP
- Caramel liquid flavour
- Honey liquid flavour
- Pure natural honey
- Purified Water BP

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C. Protect from light

6.5 Nature and contents of container

Amber glass bottle containing 100ml and 60ml Coscof. Supplied with a measuring spoon

6.6 Special precautions for disposal and other handling

Not applicable.

7 Marketing Authorization Holder

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8 Marketing Authorization Number

H1988/4748

9 Date of First Authorization/Renewal of Authorization

Date of First Authorization: 10th December, 1999
Date of Latest Renewal of Authorization: 13th May 2024

10 Date of Revision of Text

January, 2026