SUMMARY OF PRODUCT CHARACTERISTICS

1 Name of the Medicinal Product

1.1 Proprietary Name

Coscof-DM Linctus

1.2 Strength

Each 5 ml contains**:**

Chlorphenamine Maleate BP ……..….. 2mg

Sodium Citrate BP 44mg Pseudoephedrine HCl BP ….. 30mg

Dextromethorphan Hydrobromide BP ……10mg

Menthol USP …… 1mg

1.3 Pharmaceutical form

Linctus

2 Qualitative and Quantitative Composition

Each 5 ml contains**:**

Chlorphenamine Maleate BP ……..….. 2mg

Sodium Citrate BP 44mg Pseudoephedrine HCl BP ….. 30mg

Dextromethorphan Hydrobromide BP ……10mg

Menthol USP …… 1mg

For full list of excipients, see section 6.1 of SmPC

3 Pharmaceutical Form

Linctus

Clear red viscous liquid with a characteristic odor, free from visible evidence of contamination.

4 Clinical Particulars

4.1 Therapeutic Indications

COSCOF-DM 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 Dextromethorphan Hydrobromide helps relieve the discomfort or nuisance of frequent unproductive cough. COSCOF-DM is useful in both children and adults as a cough suppressant.

4.2 Posology and Method of administration

Posology

Adults and children over 12 years: Two 5mL spoonful (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) three to four times daily

Method of Administration For oral administration.

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. Caution should be taken when administering to patients who are hypersensitive to any of the excipients listed

4.5 Interaction with other medicinal products and other forms of interaction

Do not use if you are now taking a prescription selective serotonin reuptake inhibitor (SSRI), tricyclic antidepressants (TCAs) or other medications for depression, psychiatric, or emotional conditions, or Parkinson's disease. Do not use if you are taking or have taken in the past two weeks, monoamine oxidase inhibitors (MAOI's), usually used to treat depression. If you are not sure if your prescription medication contains one of these drugs, ask a doctor or pharmacist before taking this product.

CYP2D6 inhibitors

Dextromethorphan is metabolized by CYP2D6 and has an extensive first-pass metabolism. Concomitant use of potent CYP2D6 enzyme inhibitors can increase the dextromethorphan concentrations in the body to levels multifold higher than normal. This increases the patient's risk for toxic effects of dextromethorphan (agitation, confusion, tremor, insomnia, diarrhoea and respiratory depression) and development of serotonin syndrome. Potent CYP2D6 enzyme inhibitors include fluoxetine, paroxetine, quinidine and terbinafine. In concomitant use with

quinidine, plasma concentrations of dextromethorphan have increased up to 20-fold, which has increased the CNS adverse effects of the agent. Amiodarone, flecainide and propafenone, sertraline, bupropion, methadone, cinacalcet, haloperidol, perphenazine and thioridazine also have similar effects on the metabolism of dextromethorphan. If concomitant use of CYP2D6 inhibitors and dextromethorphan is necessary, the patient should be monitored and the dextromethorphan dose may need to be reduced.

Alcohol

A dose of 10ml of this medicine administered to an adult weighing 70 kg would result in exposure to 2.8 mg/kg of ethanol which may cause a rise in bloodalcohol concentration (BAC) of about 0.4mg/100 ml.

A dose of 10ml of this medicine administered to a child over 12 years of age and weighing 40 kg would result in exposure to 4.9 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 0.8 mg/100 ml

For comparison, for an adult drinking a glass of wine or 500 ml of beer, the
BAC is likely to be about 50 mg/100 ml. Co-administration with medicines containing e.g. propylene glycol or ethanol may lead to accumulation of ethanol and induce adverse effects, in particular in young children with low or immature metabolic capacity.

4.6 Fertility, Pregnancy and lactation

Fertility

There are no relevant clinical data available regarding effects on fertility from patients taking dextromethorphan. Studies in rats have demonstrated a lack of adverse effect on fertility (see section 5.3). Therefore, no adverse effects on human fertility are expected at therapeutically relevant doses.

Pregnancy

There are no relevant clinical data available regarding effects on pregnancy from patients taking dextromethorphan. Animal studies do not indicate embryofetal toxicity (see section 5.3). Dextromethorphan should not be used during pregnancy without medical advice.

Breastfeeding

Avoid the use of the product during lactation, unless the benefits to the mother outweigh the risks to the infant. If used, the lowest effective dose and shortest duration of treatment should be considered.

Dextromethorphan is excreted in breast milk in minor quantities. There is a lack of data available on the effect of infant exposure through breast milk.

4.7 Effects on ability to drive and use machines

This medicine can impair cognitive function and can affect a patient's ability to drive safely. This class of medicine is in the list of drugs included in regulations under 5a of the Road Traffic Act 1988. When taking this medicine, patients should be told:

- The medicine is likely to affect your ability to drive
- Do not drive until you know how the medicine affects you

4.8 Undesirable effects

The following convention has been utilised for the classification of the frequency of adverse reactions: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000), very rare (<1/10,000), not known (cannot be estimated from available data).

Whenever possible, adverse reactions observed in clinical trials and those reported from post-marketing experience at therapeutic/labelled doses have been presented separately. These reactions are tabulated by MedDRA System Organ Class (SOC).

The following adverse events have been observed in clinical trials with dextromethorphan.

Gastrointestinal Disorders:

Gastrointestinal upset, nausea, vomiting, abdominal discomfort Nervous System Disorders:

Dizziness, drowsiness, mental confusion

Adverse reactions identified during post-marketing use are listed below. As these reactions are reported voluntarily from a population of uncertain size, the frequency of these reactions is unknown.

Immune System Disorders:

Hypersensitivity

Psychiatric Disorders:

Frequency unknown: Drug dependence (see section 4.4)

Skin and Subcutaneous Disorders

Allergic reactions (e.g. rash, urticaria, angioedema)

General Disorders and Administration Site Conditions:

Frequency unknown: drug withdrawal syndrome

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 and the general public are advised to report any suspected adverse reactions to the relevant drug authority regulator, through the relevant platforms.
Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Reporting System (PvERS) https://pv.pharmacyboardkenya.org

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 Therapeutic class:
Antitussive.

ATC code: R05DA09

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 expectorant properties and plays 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.

Dextromethorphan Hydrobromide is a cough suppressant which has a central action on the centre in the medulla.

Menthol is chiefly used to relieve symptoms of bronchitis, sinusitis, and is especially useful when it is desired to liquify thick, tenacious sputum

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 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 gastrointestinal 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.

Dextromethorphan is rapidly absorbed from the gastro-intestinal tract. It is metabolised in the liver and excreted in the urine as unchanged dextromethorphan and demethylated metabolites including dextrorphan.

After absorption, menthol is excreted in the urine and bile as a glucuronide

5.3 Preclinical Safety Data

Non-clinical safety data on dextromethorphan obtained from the literature and in-house have not revealed findings which are of relevance to the recommended dosage and use of the product.

Reproductive and developmental toxicity

No adverse effects on male and female fertility or postnatal development were observed rats following oral administration of up to 50 mg/kg/day dextromethorphan. No effects on embryofetal development were observed in both rats and rabbits following oral administration of up to 50 mg/kg/day dextromethorphan during pregnancy. A 50 mg/kg/day dose in rats and rabbits is approximately 5- and 11-times the maximum human equivalent therapeutic dose (based on the body weight of 12-year-old child of 40 kg), respectively.

6 Pharmaceutical Particulars

6.1 List of Excipients

Potassium Sorbate BP

Sodium benzoate BP

Sodium Citrate BP

Saccharin Sodium BP

Liquid Glucose NF

Sorbitol Solution 70%

BP Natrosol 250 HX-

PHARM Citric Acid Anhydrous BP

Menthol USP

Rectified Spirit

Carmoisine Water Soluble Honey liquid flavour Raspberry liquid flavour Vanilla liquid flavour Pure natural honey

Purified Water BP

6.2 Incompatibilities None

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 30˚C. Protect from light and moisture.

6.5 Nature and contents of container

Amber glass bottle containing 100ml and 60ml Coscof-DM Expectorant Syrup.

Supplied with a measuring spoon in unit cartons with literature insert

Available in pack sizes of 60ML AND 100ML

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed off in accordance with local requirements.

7. Marketing Authorization Holder

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8. Marketing Authorization Number

18034

9. Date of First Registration/Renewal of Registration

Date of First Registration: 28th January 2008

10. Date of Revision of Text

December 2025