SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product:

1.1 Product Name :

MUCOCOF SYRUP (Diphenhydramine Hcl, Ammonium Chloride, Sodium Citrate, Codeine Phosphate & Menthol Syrup)

1.2 Strength:

Each 5 ml contains:

Diphenhydramine HCL B.P. : 10 mg

Ammonium Chloride B. P. : 90 mg

Sodium Citrate B.P. : 40 mg

Codeine Phosphate B.P. : 9 mg

& Menthol B.P.

Syrupy Base : q.s.

Colour: Sunset Yellow Supra

1.3 Pharmaceutical Dosage Form :

Liquid dosage form for oral use (Syrup)

2. Quality and Quantitative Composition

Each 5 ml contains:

Diphenhydramine HCL B.P. : 10 mg

Ammonium Chloride B. P. : 90 mg

Sodium Citrate B.P. : 40 mg

Codeine Phosphate B.P. : 9 mg

& Menthol B.P.

Syrupy Base : q.s.

Colour: Sunset Yellow Supra

2.1 Qualitative Declaration:

Diphenhydramine HCL B.P.

Ammonium Chloride B. P.

Sodium Citrate B.P.

Codeine Phosphate B.P.

& Menthol B.P.

For Excipients see section 6.1

2.2 Quantitative Declaration:

Each 5 ml contains:

Diphenhydramine HCL B.P. : 10 mg

Ammonium Chloride B. P. : 90 mg

Sodium Citrate B.P. : 40 mg

Codeine Phosphate B.P. : 9 mg

& Menthol B.P.

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For Excipients see section 6.1

3. Pharmaceutical Form: Liquid dosage form for oral use (Syrup)

4. Clinical Particulars

4.1 Therapeutic indications:

MUCOCOF SYRUP is indicated in the treatment of dry and irritating cough, imitative and spasming cough, acute and chronic bronchitis, cough in inflammatory disease of the upper respiratory tract, Tracheobronchitis.

4.2 Posology and method of administration:

Route: Oral

Adults: 5 to 10 ml every 4 to 6 hours

Children: (1 to 12 years of age) 2.5 ml to 5 ml every 4 to 6 hours.

Method of administration: Oral use only

4.3 Contraindications

Sensitivity to the any of components. Patients with impaired renal or hepatic function. Patients with respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion, after operations on the biliary tract, acute alcoholism, head injuries and conditions in which intracranial pressure is raised. It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease.

4.4 Special warning and precautions for use:

The use of this medicine may lead to drowsiness and impaired concentrations, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants hazardous tasks where loss of concentration may lead to accidents.

Precautions:

Use with caution in moderate to severely decreased kidney function.

Not to be used in cessation of breathing (respiratory failure).

Children under six years of age, Closed angle glaucoma, Liver failure & Symptoms of an enlarged prostate (symptomatic prostatic hypertrophy)

MUCOCOF SYRUP should not be used if you are allergic to one or any of its ingredients. Please inform your doctor or pharmacist if you have previously experienced such as allergy MUCOCOF SYRUP should be used with caution during pregnancy, and only if the expected benefit to the Mother is greater than any possible risk to the foetus. Seek medical advice from your doctor. MUCOCOF SYRUP may pass into breast milk in small amounts. It should only be used during breastfeeding if the benefit to the mother outweighs any potential risk to the nursing infant. Seek medical advice from your doctor.

When MUCOCOF SYRUP is taken with the following central nervous system depressants, the sedative effects may be increased:

- Minortranquilisers
- Neuroleptics
- Barbiturates
- Alcohol

4.5 Interaction with other medicinal products

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4.6 Fertility, Pregnancy and lactation

MUCOCOF SYRUP may pass into breast milk in small amounts. It should only be used during breastfeeding if the benefit to the mother outweighs any potential risk to the nursing infant. Seek medical advice from your doctor.

4.7 Effects on ability to drive and use Machines:

This medication may cause dizziness. If affected, do not drive a vehicle or operate machinery. If you drink alcohol, dizziness or drowsiness could be worse. Be careful driving or operating machinery until you know how MUCOCOF SYRUP affects you.

4.8 Undesirable effects:

The more common side effects of are:

- Dizziness
- Drowsiness
- Euphoria
- Nervousness

- Insomnia
- Tremors
- Blurred vision
- Skin rashes
- Dry mouth
- Nausea and vomiting
- Stomach pain
- Diarrhoea
- Urinary difficulty and retention
- Constipation

Reporting of suspected adverse reactions

Health care professionals are asked to report any suspected adverse reactions via the https://pv.pharmacyboardkenya.org

4.9 Over dosage:

In cases of over dosage supportive therapy is recommended. Gastric lavage should be carried out and a saline purgative may then be given to reduce absorption from gastro – intestinal tract. Symptomatic treatment of respiratory embarrassment should be given. If respiration is seriously depressed intravenous naloxone HCl may be required.

5. Pharmacological Properties :

5.1 Pharmacodynamic Properties :

Pharmacotherapeutic group: Cough expectorants & mucolytic

Mechanism of action

Ammonium Chloride is an expectorant due to its effect in product of respiratory tract fluid that facilitates effective cough.

Sodium Citrate is a buffering agent that has expectorant action on the respiratory mucosa.

Codeine Phosphate belongs to a group of medicines called the opioids. It suppresses the cough reflex. It is useful for clearing mucus, dust and other particles from the throat and lungs. It is important because it reduces the amount of mucus, dust and bacteria in the airways that would otherwise make breathing difficult. Codeine is used to block the cough reflex in situations where the cough serves no purpose. It does so by calming the part of the brain that governs the coughing reflex.

Diphenhydramine is a sedating antihistamine which acts on histamine H1 receptors. It also has anticholinergic actions.

5.2 Pharmacokinetic Properties

Diphenhydramine HCL BP

Absorption: Quick absorption after oral administration.

Oral bioavailability - 40% to 60%

Peak plasma concentration- 2 to 3 hours

Volume of distribution:

50 mg oral dose- 3.3 - 6.8 l/kg.

Protein Binding: 78% - 80 to 85%

Metabolism:

Diphenhydramine undergoes rapid and extensive first-pass metabolism. In particular, two successive N-demethylations occur wherein diphenhydramine is demethylated to N desmethyldiphenhydramine (the N-desmethyl metabolite) and then this metabolite is itself demethylated to N,N didesmethyldiphenhydramine (the N,N-didesmethyl metabolite).

In particular, CYP2D6 demonstrates higher affinity catalysis with the diphenhydramine substrate than the other isoenzymes identified. Consequently, inducers or inhibitors of these such CYP enzymes may potentially affect the serum concentration and incidence and/or severity of adverse effects associated with exposure to diphenhydramine

Route of elimination: The metabolites of diphenhydramine are conjugated with glycine and glutamine and excreted in urine. Only about 1% of a single dose is excreted unchanged in urine. The medication is ultimately eliminated by the kidneys slowly, mainly as inactive metabolites.

Ammonium Chloride BP

Absorption: Completely absorbed within 3–6 h. In healthy persons, absorption of ammonium chloride given by mouth was practically complete. Only 1 to 3% of the dose was recovered in the feces.

Metabolism: Ammonium ion is converted to urea in the liver; chloride ion replaces bicarbonate.

Route of elimination: Excretion: Urine

Sodium Citrate BP

Absorption: Tmax of 98-130min.

Metabolism: Citrate is metabolized to bicarbonate in the liver and plays a role as an intermediate in the citric acid cycle.

Route of elimination: Largely eliminated through hepatic metabolism with very little cleared by the kidneys.

Codeine Phosphate BP

Absorption: Readily absorbed from the gastrointestinal tract.

Peak plasma concentration: About one hour.

Plasma half-life: Between 3 and 4 hours

The conversion of codeine to morphine occurs in the liver and is catalyzed by the cytochrome P450 enzyme CYP2D6. CYP3A4 produces norcodeine and UGT2B7 conjugates codeine, norcodeine, and morphine to the corresponding 3- and 6- glucuronides.

CYP2D6 converts codeine into morphine, which then undergoes glucuronidation. Life threatening intoxication, including respiratory depression requiring intubation, can develop over a matter of days in patients who have multiple functional alleles of CYP2D6, resulting in ultra-rapid metabolism of opioids such as codeine into morphine.

5.3 Preclinical safety Data:

NA

6. Pharmaceutical Particulars:

6.1 List of Excipients

1 Sucrose

2 Sodium Methyl Paraben

3 Sodium Propyl Paraben

4 Propylene glycol

5 Sorbitol 70% Solution (Non-crystallising)

6 Citric Acid Monohydrate

7 Sunset Yellow Supra

8 Pineapple No.1

9 Orange Sweet No.1

10 Purified Water

6.2 Incompatibilities: None

6.3 Shelf life: 36 Months

6.4 Special precautions for storage:

Store below 30°C in a dry place, Protect from light.

6.5 Nature and contents of container: 120 ml amber colour pet bottle. Such 1 bottle to be packed in a carton along with pack insert.

6.6 Special Precaution for Disposal and other handling : None

7. MARKETING AUTHORISATION HOLDER

SIGNATURE HEALTHCARE LTD

Cape Business Park, Along Thika Super Highway

P.O.Box 66172-00800, Nairobi, KENYA

8. MARKETING AUTHORISATION NUMBER(S)

H2025/CTD9683/20555

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08.07.2025

10. DATE OF REVISION OF THE TEXT

08.07.2025