SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

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DR. MEYER'S COFLIN LINCTUS

1. NAME OF THE MEDICINAL PRODUCT

DR. MEYER'S COFLIN LICTUS (Chlorpheniramine Maleate B.P 2mg, Ammonium Chloride U.S.P. 80mg, Sodium Citrate U.S.P 40mg, Menthol USP 2mg, Ephedrine Hydrochloride B.P. 6mg/5ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Chlorpheniramine Maleate B.P	2mg
Ammonium Chloride U.S.P.	80mg
Sodium Citrate U.S.P	40mg
Menthol USP	2mg
Ephedrine Hydrochloride B.P.	6mg

Excipients:

Nipagin (Methyl Paraben)	12.50mg
Nipasol (Propyl Paraben)	1.25mg
Menthol solution	0.0038ml
Citric Acid Monohydrate B.P.	10mg
Sodium C.M.C* U.S.P.	42.50mg
Allura Red	0.40mg
Sucrose B.P	2500mg
Raspberry flavor	0.005ml
Purified water	q.s

For Full list of excipients refer section 6.1

3. PHARMACOLOGICAL FORM

Liquid Syrup

Clear pinkish-red viscous liquid with raspberry flavour presented in 100ml pet bottle with metallic screw cap packed in a carton

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Dr. Meyer's Coflin Linctus is a palatable preparation used for the relief of throat and chesty coughs

4.2 Posology and Method of administration

Adults and Children Over 12 Years: 10ml to be taken three times daily

Children (6 – 12 Years): 5ml to be taken three times daily

Children (2 – 5 Years): 2.5ml to be taken three times daily

If symptoms persist for more than three days, consult your doctor.

Method of administration

Oral

4.3 Contraindications

Dr. Meyer's Coflin Linctus is contraindicated in individuals with known hypersensitivity to any of the ingredients

Dr. Meyer's Coflin Linctus is contraindicated with patients hypersensitive to any of the components of the formula.

Dr. Meyer's Coflin Linctus is contraindicated to pregnant and breastfeeding mothers in high doses.

Dr. Meyer's Coflin Linctus should not be given to patients with metabolic or respiratory alkalosis

4.4 Special Warnings and Precautions for Use

Care should be taken in administration during pregnancy

Dr. Meyer's Coflin Linctus should be given with extreme caution to patients with heart failure, oedema, renal impairment, hypertension and eclampsia.

Do not take **Dr. Meyer's Coflin Linctus** and drive a car or operate machinery because it can cause drowsiness and dizziness.

Keep the medicine out of reach of children.

4.5 Interactions with other medications

Dr. Meyer's Coflin Linctus may lead to enhanced sedation with other CNS depressant. It is incompatible with Calcium Chloride, Phenobarbitone and Kanamycin.

Alcoholic drinks and certain other central nervous system depressants such as anxiolytics or hypnotics can potentiate the sedative effects of Chlorpheniramine Maleate

4.6 Pregnancy and lactation

This product should not be used during pregnancy or breastfeeding unless the potential benefit of treatment to the mother outweighs the possible risks to the developing fetus or breastfeeding infant.

Pregnancy

Use of Chlorpheniramine Maleate during the third trimester may result in reactions in the unborn child. It should not be used during pregnancy unless considered essential by a physician.

Lactation

Antihistamines including Chlorpheniramine Maleate may be secreted in the breast milk. It should not be used unless considered essential by a physician.

4.7 Effects on ability to drive and use machines

This product may cause drowsiness. If affected, the patient should not drive or operate machinery.

4.8 Undesirable effects

The common side-effects include drowsiness and dizziness

4.9 Overdose

Symptoms and signs

Chlorpheniramine Overdose

A Chlorpheniramine overdose may cause the following symptoms: Dry mouth, eyes, nose, and throat, a rapid heart rate, nausea and vomiting, agitation, rapid breathing, drowsiness, dilated pupils, flushing, fever, slowing of the digestive tract, low blood pressure, an irregular heart rhythm, confusion, hallucinations, delirium, psychosis, seizures, coma, loss of life.

Treatment

If the overdose was recent, a healthcare provider may give certain medicines or place a tube into the stomach to "pump the stomach." It is not usually recommended to induce vomiting for a chlorpheniramine overdose. Treatment may also involve supportive care, which consists of treating the symptoms that occur as a result of the overdose. For example, supportive treatment options may include:

- Fluids through an intravenous line (IV)
- Medicines to increase blood pressure, control an irregular heart rhythm, or control seizures
- Close monitoring of the heart and lungs
- A breathing tube to help with breathing
- Other treatments based on complications that occur.

Ammonium Chloride Overdose

Overdosage of Ammonium Chloride has resulted in a serious degree of metabolic acidosis, disorientation, confusion and coma.

Treatment

Should metabolic acidosis occur following overdosage, the administration of an alkalinizing solution such as sodium bicarbonate or sodium lactate will serve to correct the acidosis.

Overdosage with sodium salts may cause diarrhea, nausea and vomiting, hypernoia, and convulsions.

Particulars of its Treatment

If overdose occurs the patient should be monitored for evidence of toxicity and standard symptomatic and supportive treatment applied as necessary

Menthol

Excessive use of menthol may lead to abdominal pain, vomiting, flushed face, dizziness, weakness, tachycardia, stupor, and ataxia.

Treatment

Treatment of overdose should be symptomatic and supportive. The benefit of gastric decontamination is uncertain. Consider activated charcoal (charcoal dose: 50 g for adults; 1 g/kg for children) only if the patient presents within 1 hour of ingestion of a potentially toxic amount Seizures may be controlled with Diazepam or Thiopental Sodium. The intravenous use of Physostigmine may be efficacious in antagonising severe antichoinergic symptoms.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antitussive and expectorant combination

ATC Code: R06AA02

Mechanism of Action

Chlorpheniramine Maleate

It has weak antimuscarmic and moderate anti-serotonin and local anesthetic actions. Also it can cause CNS (Central Nervous System) stimulation or depression. These actions provide temporary relief of runny nose, sneezing and watery and itchy eyes.

Ammonium Chloride

It tends to lower the blood pH after being metabolized to urea and hydrochloric acid which provides hydrogen ions to acidify the blood or urine.

Sodium Citrate

It acts as an expectorant that thins the mucus.

Menthol

Menthol has mild local anaesthetic and decongestant properties.

Pharmacodynamic Effects

Chlorpheniramine Maleate

Chlorpheniramine Maleate is a potent antihistamine (H1- antagonist). It antagonizes various histamine-induced effects such as increased capillary permeability and dilation, formation of edema and the constriction of gastrointestinal and respiratory smooth muscle.

Ammonium Chloride

Ammonium chloride has irritant effect on mucous membrane and is considered to have expectorant properties.

Sodium Citrate

The effect of sodium citrate is that it renders the urine to become less acidic. It is an antitussive and mucolytic agent that breaks down the mucus so that coughing up phlegm becomes easier. It acts as an expectorant that thins the mucus.

Menthol

Menthol has mild local anaesthetic and decongestant properties.

5.2 Pharmacokinetic properties

Chlorpheniramine Maleate

i. **Absorption**
After oral administration, the absorption of chlorpheniramine maleate occurs. This is whereby plasma concentrations take place peak at about 2.5 to 6 hours. Then it is absorbed by the gastrointestinal tract.
The effects that may develop within 30 minutes are maximal within 1 to 2 hours and lasts 4 to 6 hours.

ii. **Distribution**
It is distributed in the body and taken to the CNS.

iii. **Metabolism**
It undergoes the first pass of metabolism and enterohepatic recycling. It extensively metabolized, principally to inactive desmethylated metabolites which are excreted primarily in the urine.

iv. **Excretion**
Chlorpheniramine maleate is excreted in the urine and faeces. The mean elimination half-life has been reported to be about 30 hours with mean values ranging from 2 to 43 hours.

Ammonium Chloride

i. **Absorption**
Ammonium chloride is also absorbed by the gastrointestinal tract. Following oral administration, it is rapidly absorbed from the gastrointestinal tract whereby complete absorption occurs within 3 to 6 hours.

ii. **Metabolism**
In a test carried out on healthy male and female volunteers, they were orally administered with ammonium chloride. They produced transient increase in blood pH. Those who suffered from cirrhosis showed a greater and more prolonged increase over a higher baseline. This means that their livers metabolized ammonium chloride to from urea and hydrochloric acid.

iii. **Excretion**
Ammonium chloride is excreted by the kidneys in form of urine.

Sodium Citrate

i. Absorption and Excretion

Sodium citrate is absorbed and renally eliminated causing metabolic alkalosis and urinary alkalization in sufficient doses.

Menthol

i. Metabolism and Elimination:

Menthol is hydroxylated in the liver by microsomal enzymes to p-methane -3,8 diol. This is then conjugated with glucuronide and excreted both in urine and bile as the glucuronide

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber in addition to that included in other sections of he summary of product characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Nipagin (Methyl Paraben)	12.50mg
Nipasol (Propyl Paraben)	1.25mg
Menthol solution	0.0038ml
Citric Acid Monohydrate B.P.	10mg
Sodium C.M.C* U.S.P.	42.50mg
Allura Red	0.40mg
Sucrose B.P	2500mg
Raspberry flavor	0.005ml
Purified water	q.s

6.2 Incompatibilities

None known

6.3 Shelf-Life

36 Months

6.4 Special Precautions for Storage

Store below 30° C. Replace cap securely.

6.5 Nature and Contents of Container

Dr. Meyer's Coflin Linctus is packed in 100ml amber coloured PET bottles that are sealed with 25mm ropp aluminium caps and labelled. Then the filled, sealed and labelled bottles are packed in unit cartons made of chipboard.

6.6 Instructions for Handling

None specific.

7. Applicant / Manufacturer:

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Ikeja, Lagos,
Nigeria.