

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

Simple Linctus

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Citric Acid Monohydrate BP 125mg per 5ml.

### Excipients with known effects

Sucrose 4g per 5ml.

For the full list of excipients, see section 6.1

## **3. PHARMACEUTICAL FORM**

Linctus

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic Indications**

For relief of the symptoms of coughs.

### **4.2 Posology and Method of administration**

Oral.

#### Recommended Doses

Adults, the elderly and children over 12 years: One 5ml spoonful, repeated up to four times per day.

Children under 12 years: Not recommended.

#### **4.3 Contra-Indications**

None Known.

#### **4.4 Special Warnings and Special Precautions For Use**

Keep out of the reach of children.

Not suitable for children under 12 years.

This product contains 4g of sucrose per dose. To be taken into account in people with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains less than 1mmol sodium (23 mg) per 5ml dose, that is to say essentially 'sodium-free'. This medicine contains 2.5mg sodium benzoate per 5ml dose.

#### **4.5 Interactions with other Medicinal Products and other Forms of Interaction**

None known.

#### **4.6 Pregnancy and Lactation**

No adverse effects are known for the product, however, as with all medicines use should be avoided during pregnancy unless recommended by a doctor.

#### **4.7 Effects on Ability to Drive and Use Machines**

None known.

## 4.8 Undesirable effects

### Tabulated list of adverse reaction(s)

Adverse reactions frequency are defined using the following convention:

Very common ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); rare ( $\geq 1/10,000$  to  $< 1/1,000$ ); very rare ( $< 1/10,000$ ), not known (cannot be estimated from the available data).

System organ class (MedDRA)	Frequency	Adverse event
Immune System Disorders	Not known	Hypersensitivity

### **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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

## 4.9 Overdose

Overdose with this preparation is unlikely to occur due to the low concentrations of the ingredients, however, in the event, treatment should be symptomatic.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic Properties

None stated.

## **5.2 Pharmacokinetic Properties**

None stated.

## **5.3 Preclinical Safety Data**

None.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Anise flavour (contains propylene glycol)

Sodium benzoate (E211)

Glycerol (E422)

Purified water

Syrup (sucrose)

## **6.2 Incompatibilities**

None.

## **6.3 Shelf life**

36 months unopened. Discard 2 months after first opening.

**6.4 Special Precautions for Storage**

Store below 25°C.

**6.5 Nature and contents of container**

200ml: Amber glass bottle with plastic cap and liner or white 28mm cap with tamper evident band and EPE Saranex liner

**6.6 Instructions for Use, Handling and Disposal**

None.

**7. MARKETING AUTHORISATION HOLDER**

L.C.M. Ltd  
Linthwaite Laboratories  
Huddersfield  
HD7 5QH

**8. MARKETING AUTHORISATION NUMBER(S)**

PL 12965/0032

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

21.04.1999

**10 DATE OF REVISION OF THE TEXT**

07/09/2020