

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Simple Linctus Paediatric Sugar Free

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Simple Linctus Paediatric Sugar Free: Citric Acid Monohydrate 31.25 mg/5 ml equivalent to 28.57 mg/5 ml Anhydrous Citric Acid

3 PHARMACEUTICAL FORM

Clear Sugar Free Syrup

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the management of a mild non-specific cough.

4.2. Posology and Method of Administration

Children: one or two 5 ml spoonfuls orally 3-4 times daily.
Adults: Not appropriate.

4.3 Contra-Indications

Not known.

4.4 Special warnings and precautions for use

This medicine contains maltitol liquid. Patients with rare hereditary problems of fructose intolerance should not take this medicine

This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per 5ml dose.

4.5 Interaction with other medicinal products and other forms of interaction

None Known

4.6. Pregnancy and Lactation

Not appropriate.

4.7. Effects on Ability to Drive and Use Machines

Not applicable.

4.8 Undesirable effects

Immune system disorders: Not Known: Hypersensitivity reactions including facial oedema (mainly swollen lips and/or mouth) and rash have been reported.

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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

Sufficient prolonged overdose of citric acid may cause erosion of the teeth and have a local irritant action.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Absorption: Citric Acid Monohydrate is absorbed after oral administration.

Distribution: Citric Acid is found naturally in the body and is widely distributed, about 70% of the citric acid in the body is in hard bone and this accounts for 1.5% of bone content.

Metabolic Reactions: It is an important intermediate in carbohydrate metabolism and its major role is in the tricarboxylic acid cycle (Krebs citric acid cycle); it is metabolised to carbon dioxide and water.

Excretion: Citric acid is normally excreted in the urine in amounts ranging from 0.4 to 1.5g daily and this amount is not increased unless very large doses are administered. The urinary excretion of citric acid is increased in alkaline urine.

5.2. Pharmacokinetic Properties

Not applicable.

5.3. Pre-clinical Safety Data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients(per 5ml)

Glycerol (E422)
Sodium Carboxymethylcellulose
Sodium Benzoate (E211)
Saccharin Sodium (E954)
Maltitol liquid (E965)
Ethanol (96%)
Star Anise Oil
Purified Water

6.2. Incompatibilities

Not appropriate.

6.3. Shelf Life

2 years.

6.4 Special precautions for storage

Store below 25°C

6.5. Nature and Contents of Container

Amber glass bottles with pilfer screw closure.

High density Polyethylene with screw on closure.

Pack sizes of 100 ml, 125 ml, 200 ml for Amber Glass Bottles.

Pack size of 2000 ml for High Density Polyethylene dispensary pack.

6.6. Instructions for Use/Handling

As with all medicines.

7 MARKETING AUTHORISATION HOLDER

Pinewood Laboratories Limited

Ballymacarbry

Clonmel

Co Tipperary

8. MARKETING AUTHORISATION NUMBER(S)

PL 04917/0007

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/03/2003

10 DATE OF REVISION OF THE TEXT

12/09/2019