SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Simple Linctus Paediatric

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Citric Acid Monohydrate 31.25mg/5ml dose.

Excipient(s) with known effect:

Sucrose (Syrup) 4.4g/5ml dose
Sodium Benzoate(E211) 2.5mg/5ml dose

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral Solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief of non productive (dry) coughs

4.2 Posology and method of administration

Dose

Children:

1 to 5 years: Give one 5ml spoonful
6 to 12 years: Give two 5ml spoonfuls
Repeat up to four times a day if necessary.

4.3 Contraindications

Known hypersensitivity to any of the ingredients

4.4 Special warnings and precautions for use

Keep out of the sight and reach of children.

Consult a doctor if symptoms persist for more than 5 days

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Excipient warnings:

This medicine contains 4.4g of sucrose per 5ml. This should be taken into account in patients with diabetes mellitus.
This medicine contains 2.5mg sodium benzoate per 5ml dose.
This medicine contains less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

There are no or limited amount of data from the use of citric acid monohydrate in pregnant women.

Animal studies are insufficient with respect to reproductive toxicity (see section 5.3).

There is insufficient information on the excretion of citric acid monohydrate metabolites in human milk.

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 (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 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 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

Pharmacotherapeutic Group: Acid Preparations
ATC Code: A09 AB

5.2 Pharmacokinetic properties

Citric acid is absorbed after oral administration. It is found naturally in the body and is widely distributed. It is metabolised to carbon dioxide and water in Kreb's citric acid cycle. 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.

5.3 Preclinical safety data

No data of relevance, which is additional to that included on other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anise flavour (contains propylene glycol (E1520))

Sodium benzoate (E211)

Glycerol (E422)

Purified Water

Sucrose (Syrup)

6.2 Incompatibilities

None

6.3 Shelf life

36 months unopened, 3 months after first opening

6.4 Special precautions for storage

Store below 25ºC

6.5 Nature and content of container

200ml: Amber glass bottle with a white 28mm child resistant cap with tamper evident band and EPE/Saranex liner

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd.

Linthwaite Laboratories

Huddersfield

HD7 5QH

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/6427R

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/06/1988 / 09/09/1993

10 DATE OF REVISION OF THE TEXT

21/10/2020