

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SIMPLE LINCTUS (ADULT) COUGH SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml Syrup contains:

Citric Acid Monohydrate BP125 mg

Excipients with known effects

Sucrose 4g per 5ml.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

SIMPLE LINCTUS (ADULT) COUGH SYRUP supplied in Clear coloured of 100ml round, amber plastic coloured bottle bearing product label, sealed with Aluminum ROPP cap and placed in a skilnet box bearing product information

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief of the symptoms of coughs.

4.2 Posology and method of administration

Posology

Oral.

Recommended Doses

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

Paediatric Population:

Children under 12 years: Not recommended

4.3 Contraindications

None Known

4.4 Special warnings and 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 Interaction with other medicinal products and other forms of interaction

Tell your doctor or pharmacist if you are taking other medicines

No drug interactions have been identified

4.6 Pregnancy and lactation

During Pregnancy

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

Lactation:

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

Fertility

No information available concerning impact of simple linctus cough syrup on fertility.

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 authorization 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 pvsafety@atlanticlifesciences-gh.com

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: None Stated

Mechanism of action

5.2 Pharmacokinetic properties

None Stated

5.3 Preclinical safety data

None Stated

6 PHARMACEUTICAL PARTICULARS

6.3 List of excipients

Sucrose

Sodium Benzoate

Methyl Paraben Sodium

Propyl Paraben Sodium

Menthol Crystal

Propylene Glycol

Sodium Saccharin

Flavour Lemon

Ethanol

Glycerine

6.4 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.5 Shelf life

36 months

6.6 Special precautions for storage

Do not store above 30°C and protect from light

Nature and contents of container <and special equipment for use, administration or implantation>

Bottles: Amber (PET) plastic bottle
Closure: HDPE, child resistant, tamper evident, EPE wadded closure
Pack sizes: 100ml
Dosing device: 2.5/5ml double ended polypropylene spoon.

Special precautions for disposal <and other handling>

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

7 MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

Manufacturer

ATLANTIC LIFESCIENCES LIMITED,

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Marketing Authorization

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8 MARKETING AUTHORISATION NUMBER

FDA/GD.215-08173

9 DATE OF FIRST AUTHORISATION OR RENEWAL

10/2024

10 DATE OF REVISION OF THE TEXT
05/2025