

1. NAME OF THE MEDICINAL PRODUCT

Bell's Healthcare Simple Linctus BP 125 mg per 5 ml Oral Solution

Numark Simple Linctus BP

Almus Simple Linctus Cough Relief 125 mg per 5 ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Citric Acid Monohydrate BP 125 mg/5 ml.

Excipients: Sucrose 4.3g per 5ml. For full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.

A clear, colourless liquid with the flavour of anise.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The management of mild non-specific cough.

4.2 Posology and method of administration

Dosage

Adults and the Elderly : One or two 5ml teaspoons daily, or as required.

Not recommended for children.

Administration

For oral use.

4.3 Contraindications

Glucose malabsorption syndrome. Glucose intolerance due to sucrose or isomaltase deficiency. Hypersensitivity to any of the constituents.

Special warnings and precautions for use

Care should be taken in patients with Diabetes mellitus.

Keep out of the reach of children.

Not suitable for children under 12 years.

4.5 Interaction with other medicinal products and other forms of interaction

Citric acid may interact with potassium tartrate, carbonates and bicarbonates which therefore should not be administered at the same time.

Fertility, 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.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

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

Citric acid is fever reducing.

5.2. Pharmacokinetic properties

Citric acid monohydrate is absorbed from the gastrointestinal tract.
Sucrose is hydrolysed in the small intestine by the enzyme sucrase and converted to dextrose and levulose, which are then absorbed.

5.3 Preclinical safety data

No relevant information additional to that already contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Star Anise Oil
Polysorbate 20
Sucrose
Water Purified

6.2 *Incompatibilities*

None known.

6.3 *Shelf life*

3 years.

6.4 *Special precautions for storage*

Store at a temperature not exceeding 25°C.

6.5 *Nature and contents of container*

100 ml, 125 ml, 150 ml, 175 ml, 200 ml, 225 ml, 250 ml, 300 ml and 500 ml in amber glass bottles with pilfer proof cap or child resistant cap.

500 ml, 1 litre and 2 litre high density polyethylene bottle with screw on cap.

Not all packs may be marketed.

6.6 *Special precautions for disposal*

Not relevant.

7 **MARKETING AUTHORISATION HOLDER**

Bell, Sons and Co (Druggists) Ltd [Trading Style – Bell's Healthcare]
Gifford House,
Slaidburn Crescent
Southport
Merseyside
PR9 9AL

8 **MARKETING AUTHORISATION NUMBER(S)**

PL 03105/0064

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

17th August 1998

10 DATE OF REVISION OF THE TEXT

29/01/2021