

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

Bell's Healthcare Cough Linctus Oral Solution

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Name of the active substance(s); each 5ml contains

Ammonium Chloride	100.0 mg
Sodium Citrate	50.0 mg
Levomenthol	7.75 mg
Squill Tincture	0.001 ml

Excipient(s) with known effect: methyl hydroxybenzoate E218

Each 10 ml dose contains 3.2 g sucrose and less than 100mg ethanol

For a full list of excipients, see section 6.1.

## **3 PHARMACEUTICAL FORM**

Oral Solution

## **4. CLINICAL PARTICULARS**

### **4.1. Therapeutic indications**

For the symptomatic relief of colds, sore throats, irritating and chesty coughs.

### **4.2. Posology and method of administration**

Oral administration

Adults: two 5 ml spoonfuls

Children (7-14 years): One 5 ml spoonfuls

Dose may be repeated three times a day and at bedtimes

### **4.3. Contra-indications**

Care should be taken when given to patients with impaired renal function or hypersensitivity to any of the active ingredients.

#### **4.4 Special warnings and precautions for use**

Shake bottle.

If symptoms persist consult your doctor.

This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per 10ml dose.

Contains sucrose and glucose. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Contains 10.0 mg methyl hydroxybenzoate E218 per 10 ml dose; may cause allergic reactions (possibly delayed).

#### **4.5 Interaction with other medicinal products and other forms of interaction**

No interactions studies have been performed.

Contains alcohol and should be avoided in patients taking other medicines known to interact with alcohol (e.g. metronidazole)

#### **4.6. Pregnancy and lactation**

No evidence that this medicine adversely affects pregnancy, however, as with all medicines it is recommended that Methodex is not taken during pregnancy.

#### **4.7 Effects on ability to drive and use machines**

No studies on the effects on the ability to drive or operate machines have been performed.

Contains alcohol. See Section 2.

#### **4.8 Undesirable effects**

Nausea and vomiting have been reported on taking large doses of some ingredients.

##### 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).

## **4.9 Overdose**

It is possible that excessive overdosing may produce nausea and vomiting.  
If this occurs, no further action should be necessary except to withdraw medication.

# **5 PHARMACOLOGICAL PROPERTIES**

## **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: other cold preparations      ATC code: R05X

Ammonium Chloride acts as an expectorant.

Sodium citrate possesses demulcent properties and helps to relieve irritable coughs.

Squill possess some expectorant properties.

Levomenthol acts as flavouring and helps to relieve symptoms of catarrh.

## **5.2. Pharmacokinetic properties**

Ammonium chloride is absorbed from the gastro-intestinal tract and is finally excreted in the urine.

Sodium citrate is absorbed in the gastro-intestinal tract and is finally excreted in the urine.

## **5.3. Preclinical safety data**

There is no preclinical data available specific to the product.

# **6 PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Eucalyptus Oil

Star Anise Oil

Ethanol

Sucrose  
Glucose  
Caramel E150c  
Methyl Hydroxybenzoate E218  
Liquid Extract of Horehound  
Tolu Tincture  
Water, purified

**6.2. Incompatibilities**

None known

**6.3. Shelf life**

36 months in unopened bottle.

**6.4. Special precautions for storage**

Do not store above 25°C

**6.5. Nature and contents of container**

White or amber glass bottles with ROPP closure and steran wads.  
60 ml, 100 ml, 150 ml, 200 ml.

**6.6. Instructions for use/handling**

Shake before use.

**7. MARKETING AUTHORISATION HOLDER**

Bell, Sons and Co.  
Gifford House  
Slaidburn Crescent  
Southport  
Merseyside  
PR9 9AL

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

PL 03105/0045

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

Date of grant 19 September 1986

Date of renewal 19 November 1993

**10    DATE OF REVISION OF THE TEXT**

04/05/2020