

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

Mentholated Bronchial Balsam  
Tixylix Chesty Cough Oral Solution

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Menthol	4.0mg/5ml
Squill Tincture	0.6ml/5ml
Liquorice Liquid Extract	0.125ml/5ml

### Excipients with known effect

Per 5ml dose:

0.37ml Alcohol (Ethanol)  
0.84ml glucose  
1.53g sucrose  
7.5mg parahydroxybenzoates (E215, E219)

For the full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Mixture.

## **4. CLINICAL PARTICULARS**

### **4.1. Therapeutic Indications**

For the symptomatic relief of productive (chesty) coughs and sore throats.

### **4.2. Posology and Method of Administration**

Oral.

#### Recommended doses

Adults, the elderly and children over 12 years: one or two 5ml spoonfuls.

Children 5-12 years: one 5ml spoonful.

#### Dosage schedule

The dose to be taken every four hours if required.

### **4.3 Contra-Indications**

Contraindicated in patients with known hypersensitivity to any of the ingredients. Also contraindicated in patients with cardiac disorders.

### **4.4 Special Warnings and Special Precautions for Use**

If symptoms persist or worsen consult your doctor.

#### Ingredients with known effects

This medicine contains 293mg of alcohol (ethanol) per 5ml dose. The amount in 5ml of this medicine is equivalent to less than 8ml beer or 3ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Contains 1.53g of sucrose per dose. 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.

This medicine contains sodium parahydroxybenzoates (E215, E219) which may cause allergic reactions (possibly delayed).

This medicine contains less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially 'sodium-free'.

### **4.5 Interactions with other Medicinal Products and other Forms of Interaction**

Toxicity of squill glycosides may be increased when given in combination with thiazides or loop diuretics, as these may cause hypokalaemia and hypomagnesaemia which may lead to cardiac arrhythmias.

When used with carbenoxolone it may produce sodium and water retention and hypokalaemia, and may give rise to greater toxicity of squill.

### **4.6 Pregnancy and Lactation**

There are no adverse reports when used in recommended doses. However, as with all medicines care should be taken when using this product in pregnancy and medical advice sought if necessary.

#### **4.7. Effects on Ability to Drive and Use Machines**

None.

#### **4.8. Undesirable effects**

Hypersensitivity reactions and gastrointestinal reactions have been reported with this product. Hypersensitivity reactions may include generalised urticaria and flushing, menthol may give rise to contact dermatitis.

Liquorice may cause sodium and water retention, and hypokalaemia.

##### **Reporting of suspected adverse reactions**

Reporting of 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) or search for 'MHRA Yellow Card' in the Google Play or Apple App Store.

#### **4.9 Overdose**

Ingestion of large doses of the active ingredients has been reported to cause the following effects: gastrointestinal disturbances such as abdominal pain, nausea, vomiting and diarrhoea would be expected to occur with the menthol and squill.

Common symptoms of digoxin overdose include headache, facial pain, fatigue, weakness, dizziness, drowsiness, disorientation, mental confusion, bad dreams and more rarely delirium, acute psychoses, and hallucinations.

Convulsions have been reported. Visual disturbances including blurred vision may occur. Colour vision may be affected with objects appearing yellow or less frequently green, red, brown, blue or white.

Adverse effects on the heart may result from the cardiac glycosides in squill.

Toxic doses may cause or aggravate heart failure. Supraventricular or ventricular arrhythmias and defects of conduction are common and may be an early indication of excessive dosage.

In addition CNS effects such as vertigo, ataxia and drowsiness have been reported after ingestion of large quantities of menthol; reported adverse effects following excessive ingestion of liquorice include hypertension, congestive heart failure, cardiac arrest, headache, muscle weakness, myopathy, myoglobinuria, paralysis, hyperprolactinaemia and amenorrhoea. In the unlikely event of overdose with this preparation, gastric lavage and / or symptomatic treatment together with supportive measures should be employed.

Treatment of acute digoxin poisoning consists of emptying the stomach by emesis or lavage. Activated charcoal may be given. Cardiac toxicity should be treated under ECG control and serum electrolytes should be monitored. Anti-arrhythmic treatment may be necessary and should be determined by the

specific arrhythmia present. Atropine may be given intravenously to control bradycardia and in patients with heart block; cardiac pacing may be necessary if atropine is not effective. Cholestyramine or colestipol may be of use in increasing the elimination of cardiac glycosides.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1. Pharmacodynamic Properties**

Menthol dilates the blood vessels causing a sensation of coldness followed by analgesic effect.

It is used to relieve the symptoms of bronchitis, sinusitis and similar conditions.

Squill has an irritant effect on the gastric mucosa, it has a reflex expectorant action.

Liquorice is a demulcent and mild expectorant.

### **5.2. Pharmacokinetic Properties**

After absorption menthol is excreted in the bile and urine as a glucuronide.

Squill glycosides are poorly absorbed from the gastro-intestinal tract, they are of short acting

duration and are not cumulative; they are excreted in the urine and faeces.

No information is available on the pharmacokinetics of liquorice.

### **5.3. Pre-clinical Safety Data**

None.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

Peppermint oil

Anise oil

Capsicum tincture

Alcohol (Ethanol)

Syrup (contains sucrose)

Liquid glucose

Veegum k

Sodium methyl hydroxybenzoate (E219)

Sodium ethyl hydroxybenzoate (E215)

Sodium propyl hydroxybenzoate

Glycerol (E422)  
Caramel (E150c)  
Purified water

## **6.2. Incompatibilities**

None known.

## **6.3. Shelf-Life**

150ml: 36 months unopened.  
200ml: 36 months unopened.

## **6.4. Special Precautions for Storage**

Store below 25°C.

## **6.5 Nature and contents of container**

150ml: amber glass bottle with plastic cap with EPE/Saranex liner or white plastic child resistant cap with EPE/Saranex liner or white 28mm cap with tamper evident band and EPE Saranex liner or white 28mm Child-resistant cap with Tamper Evident band and EPE/Saranex Liner

200ml: amber glass bottle with plastic cap with EPE/Saranex liner or white plastic child resistant cap with EPE/Saranex liner or white 28mm cap with tamper evident band and EPE Saranex liner or white 28mm Child-resistant cap with Tamper Evident band and EPE/Saranex Liner

## **6.6. Instructions for Use, Handling and Disposal**

None.

## **7. MARKETING AUTHORISATION HOLDER**

L.C.M. Ltd.,  
Linthwaite Laboratories  
Huddersfield  
HD7 5QH

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

PL: 12965/0026

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

24/03/94 / 13.04.99

**10    DATE OF REVISION OF THE TEXT**

20/03/2024