

## Summary of Product Characteristics

### 1. NAME OF THE MEDICINAL PRODUCT

Potter's Chesty Cough Pastilles  
Boots Catarrh Pastilles  
Potter's Mucus Cough Pastilles  
Superdrug Catarrh Pastilles

## SUMMARY OF PRODUCT CHARACTERISTICS

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Levomenthol	0.813 % w/w
Dwarf pine oil	0.604 % v/w
Eucalyptus oil	0.022 % v/w

Also contains a total of 0.5 g sucrose and glucose (see section 4.4. Special warnings and precautions for use).

For full list of excipients, see section 6.1

### 3. PHARMACEUTICAL FORM

Pastille (Lozenge)

### 4. CLINICAL PARTICULARS

#### 4.1. Therapeutic Indications

For the symptomatic relief of catarrh, coughs and colds.

#### 4.2. Posology and Method of Administration

*Adults, the elderly and children of 12 years and over:*  
One pastille to be sucked slowly as often as required.  
Do not take more than 20 pastilles in 24 hours.  
Not recommended for children under 12 years old

### **4.3. Contra-Indications**

Patients with known hypersensitivity to menthol, eucalyptus oil or any other of the ingredients.

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

If symptoms persist consult your doctor.

Keep out of reach of children

Dose restricted by age in any 24 hour period

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

### **4.5. Interaction with other Medicinal products and other forms of Interaction**

None reported.

### **4.6 Fertility, pregnancy and lactation**

#### *Pregnancy*

There is no or inadequate evidence of the safety of the active ingredients in this medicine in human pregnancy. The potential risk for humans is unknown.

In the absence of sufficient data, the use during pregnancy is not recommended.

#### *Lactation*

It is not known whether the active ingredients of this product are excreted in human breast milk.

In the absence of sufficient data, the use during lactation is not recommended.

#### *Fertility*

Studies on the effects on fertility have not been investigated.

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

None known.

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### 4.8 Undesirable effects

Rare reports of hypersensitivity reactions including anaphylaxis, angioedema, urticaria, bronchospasm and rash, have been reported with menthol-containing preparations.

#### **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) or search for **MHRA Yellow Card** in Google Play or Apple App Store.

### 4.9 Overdose

Symptoms of overdose are unlikely unless the product is abused and taken grossly in excess of the recommended dose; gastrointestinal irritation, nausea and vomiting might be first seen. Supportive measures would be indicated.

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## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

The decongestant activity of menthol, eucalyptus oil and dwarf pine oil is due to their volatility. Volatile oils are also said to have a mild irritant effect on the mucous membranes inducing a feeling of warmth and increasing salivation, which combined with the demulcent effect of the pastille base, helps to soothe a cough.

Eucalyptus oil and dwarf pine oil have been reported to possess antimicrobial activity which may also be of benefit.

It is claimed that eucalyptus oil also has some expectorant activity.

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### 5.2 Pharmacokinetic properties

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

Volatile oils such as eucalyptus oil and dwarf pine oil are excreted via the lungs, skin and kidneys.

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

There is no pre clinical data available specific to the product.

## **Pharmaceutical Particulars**

### **6.1. List of Excipients**

Sucrose  
Liquid Glucose  
Modified Starch (maize, tapioca)  
Thymol  
Marshmallow Root Liquid Extract  
Carmoisine E122  
Vegetable Oil  
Carnauba wax  
Water

### **6.2. Incompatibilities**

None known.

### **6.3. Shelf Life**

36 months

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

Do not store above 25°C. Store in the original package.

### **6.5. Nature and Contents of Container**

#### **Blister Pack**

Blister strips of 250µm PVC coated 60g/m<sup>2</sup> PVDC with 20µm hard temper aluminium foil in a carton.

Pack Sizes: 4, 6, 8, 10, 12, 20, 24, 30 pastilles.

Not all pack sizes may be marketed

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

None specific to the product or pack.

**7. MARKETING AUTHORISATION HOLDER**

Ernest Jackson & Co Ltd  
High Street  
Crediton  
Devon EX17 3AP  
UK

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

PL 00094/0009

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

12 December 1991 / Renewed 29 November 1996

**10. DATE OF REVISION OF THE TEXT**

08/01/2024