

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Dequacaine Lozenges  
Benzocaine 10 mg  
Dequalinium chloride 0.25 mg

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 0.25 mg dequalinium chloride and 10 mg benzocaine

### Excipients:

Sorbitol (E420)  
Sugar base (consisting of glucose and sucrose) 2.6g/lozenge.

*For full list of excipients, see section 6.1*

## 3 PHARMACEUTICAL FORM

Lozenge.  
Round, yellow lozenges.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the relief of severe sore throats and for the relief of pain and discomfort in the oral cavity associated with superficial infection of the oropharynx or with dental procedures.

### 4.2 Posology and method of administration

#### Adults and children over 12 years:

One lozenge to be sucked slowly every two hours as required. Not more than 8 lozenges to be taken in any 24 hours.

#### Children under 12 years:

Not suitable.

#### Elderly:

There is no need for dosage reduction in elderly.

### 4.3 Contraindications

Patients sensitive to any of the ingredients or to para-aminobenzoic acid and its derivatives.

Patients with low plasma cholinesterase concentrations.

### 4.4 Special warnings and precautions for use

Speak to your doctor before use if you are pregnant, breast feeding, taking any medicines (especially sulphonamides) or suffer from Myasthenia Gravis.

The label states:

Warning: Do not exceed the stated dose. Keep all medicines out of the reach of the children. If symptoms persist or are accompanied by fever, headache, nausea or vomiting consult your doctor.

Patients with rare heredity 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**

Dequacaine is contraindicated in those patients taking anticholinesterases.

Benzocaine is metabolised to para-aminobenzoic acid and Dequacaine may therefore antagonise the effects of sulphonamides.

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

The safety of Dequacaine during pregnancy and lactation has not been established. As local anaesthetic can cross the placenta, it is recommended that this product is not taken during pregnancy. No information on the use of this product in lactation is available and it is recommended that Dequacaine is not taken while breast feeding.

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

No adverse effects known.

#### **4.8 Undesirable effects**

Dequacaine may occasionally cause hypersensitivity reactions. Methaemoglobinaemia has occasionally been reported following the use of benzocaine.

#### **4.9 Overdose**

Symptoms of overdosage including yawning, restlessness, excitement, nervousness, dizziness, nystagmus, tinnitus, blurred vision, nausea, vomiting, muscle twitching, tremors and convulsions. Excitation may be transient and followed by depression with drowsiness, respiratory failure and coma. There may be simultaneous effects on the cardiovascular system with myocardial depression and peripheral vasodilation, resulting in hypertension, arrhythmias and cardiac arrest. May also cause methaemoglobinaemia.

Treatment consist essentially of maintaining the circulation and respiration and controlling convulsions. The circulation may be maintained with infusions of plasma or suitable electrolyte solutions.

Convulsions may be controlled with the infusions of plasma or suitable electrolyte solution. Convulsions may be controlled by the intravenous administration of diazepam.

If necessary, suxamethonium together with endotracheal intubation and artificial respiration may be used if convulsions persists.

Metahemoglobinaemia may be treated by intravenous administration of 1-4 mg/kg methylene blue injection.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Benzocaine is a local anaesthetic of the ester type. Dequalinium chloride is a quaternary ammonium antiseptic active against many gram-positive and gram-negative bacteria, yeasts and fungi.

## **5.2 Pharmacokinetic properties**

Benzocaine is readily absorbed through mucous membranes and is hydrolysed by esterases in the plasma and to a lesser extent in the liver.

## **5.3 Preclinical safety data**

There are no preclinical safety data of relevance to the consumer.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium saccharin  
Levomenthol  
Racemic camphor  
Peppermint oil  
Benzyl alcohol  
Sorbitol (E420)  
Sugar base (sucrose and glucose)

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

2 years.

### **6.4 Special precautions for storage**

Do not store above 30°C

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

PVC/PVDC blister strips sealed with aluminium foil enclosed in cardboard cartons to give a pack of 24 lozenges.

### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Reckitt Benckiser Ireland Ltd  
7 Riverwalk  
Citywest Business Campus  
Dublin 24

## **8 MARKETING AUTHORISATION NUMBER**

PA 0979/035/001

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

Date of first authorisation: 27 July 1987

Date of last renewal: 26 August 2006

**10 DATE OF REVISION OF THE TEXT**

February 2014