

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Anbesol Anaesthetic Antiseptic

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine Hydrochloride	0.90	% w/w
Chlorocresol	0.10	% w/w
Cetylpyridinium Chloride	0.02	% w/w
Ethanol	68.239	% w/w

For excipients, see 6.1.

#### 3 PHARMACEUTICAL FORM

Oromucosal Solution  
A clear yellow liquid.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

Properties:

A local anaesthetic/antiseptic combination.

Indications for use:

In the symptomatic relief of mouth ulcers and sore gums.

##### 4.2 Posology and method of administration

For patients of 10 years and over:

Apply to the affected area 3-4 times daily or as directed by the physician or dentist.

##### 4.3 Contraindications

Patients with a known history of hypersensitivity or allergic type reactions to any of the constituents of the product.

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

The label will contain the following statements:

1. If there is no improvement in 3 days, consult your doctor or dentist.
2. Do not persist with any medication if results seem unsatisfactory, except on doctor's advice.
3. Do not exceed the stated dose.
4. Keep all medicines out of the reach of children.

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

None known.

## 4.6 Pregnancy and lactation

None known.

## 4.7 Effects on ability to drive and use machines

None stated.

## 4.8 Undesirable effects

There have been reports of non-specific ulceration following oral cetylpyridinium chloride therapy.

## 4.9 Overdose

Ingestion of the complete contents of the market pack should not be expected to cause any adverse effects.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

### Lidocaine hydrochloride:

White crystalline powder soluble in water and alcohol.

### Mechanism of action/effect:

Lidocaine is a local anaesthetic of the amide type which acts by reversible inhibition of nerve impulse generation and transmission.

### Chlorocresol:

Colourless crystals or a white crystalline powder slightly soluble in water and alcohol.

### Mechanism of action/effect:

Chlorocresol has a disinfectant action.

### Cetylpyridinium chloride:

A white unctuous powder soluble in water and alcohol.

### Mechanism of action/effect:

Cetylpyridinium chloride has a disinfectant action.

## 5.2 Pharmacokinetic properties

### Lidocaine hydrochloride:

Lidocaine is readily absorbed from mucous membranes and through damaged skin. Lidocaine undergoes first-pass metabolism in the liver and about 90% is dealkylated to form monoethylglycinexylidide and glycinexylidide. Further metabolism occurs and the metabolites are excreted in the urine with less than 10% as unchanged lidocaine.

### Chlorocresol and cetylpyridinium chloride:

Absorption: There is no significant absorption of chlorocresol or cetylpyridinium chloride through the skin or mucous membranes.

## 5.3 Preclinical safety data

Not applicable.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Levomenthol

Glycerin

Caramel Colour [Comprised of Quinoline Yellow (E104), Amaranth (E123), Sunset yellow (E110) & Green S (E142)]

Purified Water

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf Life**

3 years.

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

Do not store above 25°C.

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

Glass bottle with screw threaded wadded plastic caps containing 6.5ml or 15ml of product.

### **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**

SSL International plc

Venus

1 Old Park Lane

Trafford Park

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M41 7HA

UK

## **8 MARKETING AUTHORISATION NUMBER**

PA 1138/25/1

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

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2003

## **10 DATE OF REVISION OF THE TEXT**

April 2006