

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Betadine Swabsticks

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of impregnating solution contains 10% w/v povidone iodine, which contains 3 parts per million free iodine.

Each 3 swab packet will contain 7.0g of solution.

Each 5 swab packet will contain 14.0g of solution.

Each single swab packet contains 2.33g of impregnating solution.

For excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Swabsticks impregnated with a cutaneous solution.

Swabsticks impregnated with an aqueous iodine coloured solution.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

As an antiseptic for cleansing and preparation procedures.

##### 4.2 Posology and method of administration

For topical use only.

Swab area thoroughly. Use swab only. Use as required.

##### 4.3 Contraindications

Use in patients with a known hypersensitivity to iodine. Use in children under 2 years of age. Use in patients with thyroid disorders.

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

Use of this preparation may interfere with tests of thyroid function. Special caution is needed when regular applications to broken skin are made in patients with pre-existing renal insufficiency. Regular use should be avoided in patients on concurrent lithium therapy. If used for prolonged periods, thyroid function tests should be performed.

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

None known.

##### 4.6 Pregnancy and lactation

Regular use should be avoided in pregnant or lactating women as absorbed iodine can cross the placental barrier and can be secreted in breast milk.

## 4.7 Effects on ability to drive and use machines

Not applicable.

## 4.8 Undesirable effects

Local skin reactions can occur. Application to large wounds or severe burns, can produce systemic adverse effects such as metabolic acidosis, hypernatraemia and impairment of renal function.

## 4.9 Overdose

Due to the nature of this product, overdose is highly unlikely. However, excess iodine can produce goitre and hypothyroidism or hyperthyroidism. Systemic absorption of iodine after repeated applications of povidone iodine to large areas of wounds or burns may lead to a number of adverse effects: metallic taste in mouth, increased salivation, burning or pain in the throat or mouth, irritation, swelling of the eyes, pulmonary oedema, skin reactions, gastrointestinal upset and diarrhoea, metabolic acidosis, hypernatraemia, renal impairment. In the case of accidental ingestion of large quantities of Betadine, symptomatic and supportive treatment should be provided with special attention to electrolyte balance and renal and thyroid function.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Povidone iodine is a complex of iodine, which retains the broad spectrum germicidal activity of the elemental iodine without its disadvantages. The germicidal activity is maintained in the presence of blood, pus, serum and necrotic tissue. It is therefore suitable for use as a broad spectrum topical antiseptic for the prevention of infection in minor cuts, small areas of burns and treatment of bacterial skin infections and pyodermas, including infection i.e. decubitus and venous ulcers.

## 5.2 Pharmacokinetic properties

At the levels of iodine released from the povidone iodine complex in this presentation, little systemic absorption would be expected.

## 5.3 Preclinical safety data

None stated.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Glycerol  
Sodium hydroxide  
Igepal CO 360(nonyl phenoxy poly(ethyleneoxy) ethanol)  
Sodium phosphate dried  
Citric acid anhydrous  
Purified water

## 6.2 Incompatibilities

Not applicable.

### **6.3 Shelf Life**

3 years.

Use immediately after opening.

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

Do not store above 30 °C.

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

Cartons containing 50 individual paper/polyethylene sachets. Rayon-tipped polypropylene swabsticks. Each sachet contains 1, 3 or 5 swabsticks.

### **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**

Not applicable.

## **7 MARKETING AUTHORISATION HOLDER**

Medlock Medical Ltd.  
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## **8 MARKETING AUTHORISATION NUMBER**

PA 1175/2/17

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

Date of first authorisation: 08 March 1982

Date of last renewal: 08 March 2002

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

February 2005