

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Brush-Off Cold Sore Treatment

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Povidone Iodine 10% w/v

For excipients, see section 6.1

#### 3 PHARMACEUTICAL FORM

Cutaneous solution

A clear, reddish brown, alcoholic/aqueous solution.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

As a topical antiseptic in the prevention and treatment of topical cutaneous infections.

##### 4.2 Posology and method of administration

For topical administration.

Use once or twice daily or as directed.

Apply directly to the affected area and allow to dry. Cover with a dressing if desired.

##### 4.3 Contraindications

1. Use in patients with a known or suspected hypersensitivity to iodine.
2. Regular use in patients and users with thyroid disorders (in particular nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis).
3. Do not use on children under 2 years of age.

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

1. If symptoms persist, consult your doctor.
2. Side effects include local irritation and hypersensitivity.
3. The product should not be used near the eyes.

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

1. Absorption of iodine from povidone iodine through either intact or damaged skin may interfere with thyroid function tests.
2. Contamination with povidone iodine of several types of tests for the detection of occult blood in faeces or blood in urine may produce false positive results.

## 4.6 Pregnancy and lactation

Regular use of povidone iodine should be avoided in pregnant or lactating women as absorbed iodine can cross the placental barrier and be secreted into breast milk. Although no adverse effects have been reported from limited use, caution should be recommended and therapeutic benefit must be balanced against possible effects of the absorption of iodine on foetal thyroid function and development.

## 4.7 Effects on ability to drive and use machines

None stated.

## 4.8 Undesirable effects

Rarely, local irritation may occur.

Anaphylactic reactions, anaphylactoid reactions and anaphylactic shock have been reported uncommonly with products containing povidone-iodine or povidone.

## 4.9 Overdose

Overdose is unlikely with this product. However, in the cases of accidental ingestion of large quantities of Brush-Off Cold Sore Treatment, symptomatic and supportive treatment should be provided with special attention to electrolyte balance and thyroid function.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Povidone-iodine is a complex of iodine which shows all the broad spectrum germicidal activity of elemental iodine. The germicidal activity is maintained in the presence of blood, pus, serum and necrotic tissue. It is effective in the treatment of infections caused by bacteria, fungi, yeasts and viruses (e.g. Herpes Virus Types I and II).

## 5.2 Pharmacokinetic properties

None stated.

## 5.3 Preclinical safety data

None stated.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Glycerol  
Nonoxynol 9  
Dibasic Sodium Phosphate (anhydrous)  
Citric Acid monohydrate (E330)  
Industrial Methylated Spirit  
Sodium Hydroxide (10% Solution)  
Purified Water

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf Life**

Three years.

## **6.4 Special precautions for storage**

Store below 25°C. Store in the original container.

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

Glass bottle (Type III) with applicator brush containing 8 ml of product.

## **6.6 Instructions for use and handling**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Seton Healthcare Group plc  
Tubiton House  
Oldham  
OL1 3HS  
England

## **8 MARKETING AUTHORISATION NUMBER**

PA 696/5/1

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

Date of first authorisation: 2<sup>nd</sup> June 1988

Date of last renewal: 2<sup>nd</sup> June 2003

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

March 2004