

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Betadine Ear Drops.

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Povidone Iodine 5 % w/v

For excipients, see section 6.1

#### 3 PHARMACEUTICAL FORM

Ear drops, solution.

Iodine-coloured, clear, aqueous solution.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

As an antiseptic for the management of superficial ear infections.

##### 4.2 Posology and method of administration

For topical administration.

Three to four drops instilled by dropper four times daily, or as directed by the physician.

##### 4.3 Contraindications

1. Use in patients who are iodine-sensitive.
2. Use in patients with perforated ear drum.

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

Care must be taken when applying the product to areas of broken skin, as excessive absorption of iodine may occur.

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

None stated.

##### 4.6 Pregnancy and lactation

Use in pregnancy and lactation should be limited and although no adverse effects are anticipated when used at the recommended dose, caution is 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

Povidone iodine may produce local skin reactions although it is considered to be less irritant than iodine.

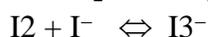
#### 4.9 Overdose

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

The active ingredient, povidone iodine slowly liberates iodine when in contact with skin and mucous membranes. The activity of iodine as a microbicide is then governed by a series of dissociations.



The microbicidal species  $H_2O I^+$  preferentially displaces  $O_2$  as the end electron acceptor in the micro organisms respiratory cycle.  $H_2O I^+$  similarly interacts within the electron transport chain and reacts with the amino acids of the microbial cell membrane.

#### 5.2 Pharmacokinetic properties

Not relevant to topical products.

#### 5.3 Preclinical safety data

None stated.

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Glycerol  
Dried disodium phosphate  
Citric acid (anhydrous)  
Sodium chloride  
Polyoxyethylated nonylphenol  
Sodium hydroxide solution  
Purified water

#### 6.2 Incompatibilities

Not applicable.

### **6.3 Shelf Life**

Three years.

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

Do not store above 25°C.

Store container in outer carton.

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

12 ml round, amber glass bottle, fitted with dropper assembly.

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

None.

## **7 MARKETING AUTHORISATION HOLDER**

Seton Healthcare Group plc  
Tubiton House  
Oldham  
OL1 3HS  
England

## **8 MARKETING AUTHORISATION NUMBER**

PA 696/2/9

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

Date of first authorisation: 28<sup>th</sup> July 1975

Date of last renewal: 27<sup>th</sup> July 2001

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

September 2001