

## Summary of Product Characteristics

### 1 NAME OF THE MEDICINAL PRODUCT

Betadine Skin Cleanser 40mg/ml cutaneous solution

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 40 mg povidone iodine.

For excipients see Section 6.1.

### 3 PHARMACEUTICAL FORM

Cutaneous Solution.

Golden brown, clear viscous liquid.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic Indications

For the disinfection and cleansing of skin in the management of superficial infections.

#### 4.2 Posology and method of administration

Apply to thoroughly wet skin, then rinse, twice daily or as directed by a physician.

#### 4.3 Contraindications

Use in patients with hypersensitivity to iodine.

#### 4.4 Special warnings and precautions for use

Use of the preparation may interfere with tests of thyroid function.

If there is aggravation of the condition or no improvement consult the doctor.

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

None stated.

#### 4.6 Fertility, 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 can be secreted into breast milk.

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

None known.

#### 4.8 Undesirable effects

Use of this preparation may interfere with tests of thyroid function.

## 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 imbalance and renal and thyroid function.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

D08AG02-Antiseptics and disinfectants

Betadine Skin Cleanser contains povidone-iodine, a complex of iodine which shows all the broad spectrum germicidal activity of elemental iodine.

### 5.2 Pharmacokinetic properties

Not applicable.

### 5.3 Preclinical safety data

Not applicable.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Potassium iodate  
Sulphated nonoxynol  
Lauric diethanolamide  
Hydroxyethylcellulose  
Perfume Vah Floral No. 2  
Sodium hydroxide  
Purified water

### 6.2 Incompatibilities

None stated.

### 6.3 Shelf life

3 years.

### 6.4 Special precautions for storage

Do not store above 25°C.  
Store in the original container.

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

Polypropylene bottles with polypropylene screw caps containing 125 or 250ml of product.

Not all pack sizes may be marketed.

## **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**

Ayrton Saunders Ltd  
9 Arkwright Road  
Astmoor Industrial Estate  
Runcorn  
Cheshire WA7 1NU  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER**

PA 0501/006/008

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

Date of first authorisation: 25<sup>th</sup> November 1975

Date of last renewal: 25<sup>th</sup> November 2005

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

December 2011