

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Iodine Liniment Strong, Cutaneous Solution  
Iodine 10% w/v  
Potassium Iodide 6% w/v

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Iodine 10% w/v and Potassium Iodide 6% w/v.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cutaneous Solution.  
Iodine Liniment Strong is a brownish yellow liquid with a characteristic odour.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Antiseptic for minor cuts, wounds, and abrasions and unbroken skin.

### 4.2 Posology and method of administration

Not for use in children under 2 years (see section 4.3).

Clean the affected area. Apply topically using cotton wool. Do not cover with an occlusive dressing. Do not use for more than two weeks. When the wound has begun to heal discontinue use. If the wound has not begun to heal in two weeks, discontinue use and contact your doctor.

### 4.3 Contraindications

Do not use during pregnancy or lactation (see section 4.6).  
Hypersensitivity to the ingredient iodine or any of the excipients.  
Do not use on children under 2 years of age (see section 4.2).  
Regular use is contraindicated for children and users with thyroid disorders (in particular nodular goiter). Do not use for prolonged periods.

### 4.4 Special warnings and precautions for use

Iodine may cause sensitivity reactions. For external use only. Product should not be ingested internally. Iodine stains the skin a deep reddish-brown. Do not apply to mucous membranes.

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

Interference with thyroid function tests has occurred. The effects of iodine and iodides on the thyroid may be altered by other compounds including amiodarone and lithium.

### 4.6 Pregnancy and lactation

Iodine should be avoided in cases of pregnancy or lactating women as absorbed iodine can cross the placental barrier and can be secreted into breast milk and could affect foetal thyroid function and development. Do not use during pregnancy or lactation.

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

No adverse effects reported.

#### **4.8 Undesirable effects**

None reported.

#### **4.9 Overdose**

In acute iodine poisoning copious draughts of milk and starch mucilage should be given and the stomach emptied by aspiration and lavage with dilute starch or a 1% solution of sodium thiosulphate. The use of gastric lavage with activated charcoal has also been suggested. Electrolyte and water losses should be replaced and circulation should be maintained.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Iodine Liniment Strong Solution is used as a disinfectant and antiseptic. It has powerful bactericidal action. It is also active against fungi, viruses, protozoa, cysts and spores. Its activity is reduced in the presence of organic matter, though not to the same extent as with other halogen disinfectants.

#### **5.2 Pharmacokinetic properties**

Iodine is slightly absorbed when applied to the skin. When taken by mouth, iodine preparations which are converted to iodine and iodides are trapped by the thyroid gland. Iodides not taken up in the thyroid are excreted mainly in the urine. They cross the placenta and are excreted in breast milk.

#### **5.3 Preclinical safety data**

No preclinical studies were carried out.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Purified Water  
Ethanol (90%)

#### **6.2 Incompatibilities**

Iodine is incompatible with acetone, with which it forms an irritating compound. Incompatible with alkalis, alkali carbonates, alkaloids, ammonia, phenol, sodium thiosulphate, starch, tannins and vegetable astringents.

#### **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**

30ml glass amber bottle with polypropylene tamper evident cap.  
500ml dispensing pack glass amber bottle with a tamper evident cap.

#### **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**

Replace cap tightly when not in use.

### **7 MARKETING AUTHORISATION HOLDER**

Ovelle Limited  
Industrial Estate  
Coe's Road  
Dundalk  
Co Louth

### **8 MARKETING AUTHORISATION NUMBER**

PA 206/26/1

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

Date of first authorisation: 13 October 1992

Date of last renewal: 13 October 2007

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

October 2010