

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Betadine 10% w/w Ointment

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Iodinated Povidone 10% w/w (yielding 1% w/w available iodine)

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Ointment

Smooth, uniform, dark brown ointment.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

As a topical antiseptic for management of minor trauma or infection of the skin.

### 4.2 Posology and method of administration

Apply to the affected area, once or twice daily for a maximum of 14 days.

### 4.3 Contraindications

Hypersensitivity to iodine, polyvinylpyrrolidone or to any excipient. History of abnormal thyroid function or goitre (in particular nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis). Use in children under two years of age. Regular use should be avoided in patients on concurrent lithium therapy.

### 4.4 Special warnings and precautions for use

Use of this preparation may interfere with tests of thyroid function. Iodine is absorbed through burns and broken skin and to a lesser extent through intact skin and may lead to toxic levels of iodine in the blood, particularly in patients with renal insufficiency. If symptoms occur, suggesting changes in thyroid function, these should be investigated. In patients with impaired renal function, blood levels of iodine should be monitored.

If local irritation and hypersensitivity develop, then discontinue treatment. Refer to section 4.8, "Undesirable effects" for further information.

Betadine Ointment can permanently discolour white gold jewellery and it is recommended that this type of jewellery should be removed before using Betadine Ointment.

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

Use with concurrent lithium therapy has been shown to exhibit additive hypothyroidic effects. Absorption of iodine from povidone iodine through either intact skin or broken skin may interfere with thyroid function tests. 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 Fertility, pregnancy and lactation

Iodine freely crosses the placenta and is secreted in breast milk. Thyroid function disorders have been reported in the offspring of mothers exposed to pharmacological doses of iodine. Povidone iodine should not be used regularly during pregnancy unless there is no alternative treatment available.

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

None known

#### **4.8 Undesirable effects**

Local irritation, skin burns and sensitivity reactions have been reported rarely. Anaphylactic reactions, anaphylactoid reactions and anaphylactic shock have been reported uncommonly with products containing povidone-iodine or povidone.

Excess iodine can produce goitre and hypothyroidism or hyperthyroidism. Such effects have occasionally been seen with extensive or prolonged use of povidine iodine. Other effects that have been reported are metabolic acidosis and acute renal failure.

#### **4.9 Overdose**

Deliberate or accidental ingestion of large quantities of povidine iodine will result in high blood concentrations of iodine and gastrointestinal corrosive effects including vomiting, diarrhoea and abdominal pain. Systemic toxicity may result in shock, hypotension, tachycardia, fever, metabolic acidosis and renal impairment. Symptomatic and supportive treatment should be started with special attention to monitoring electrolyte balance, renal function, thyroid function and liver function. Haemodialysis effectively clears iodine and should be employed in severe cases of iodine poisoning particularly if renal failure is present. Continuous venovenous haemodiafiltration is less effective than haemodialysis.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

ATC Code: D08AG02 - Antiseptics and Disinfectants.

Betadine 10% w/w Ointment contains Iodinated povidone, 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. Iodinated povidone kills bacteria, viruses, fungi, spores and protozoa.

#### **5.2 Pharmacokinetic properties**

Not applicable.

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

Not applicable.

### **6 PHARMACEUTICAL PARTICULARS**

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

Macrogol 400  
Macrogol 1000  
Macrogol 1500  
Macrogol 4000  
Sodium hydrogen carbonate (E500)  
Purified water

#### **6.2 Incompatibilities**

Not applicable.

### **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**

Triple epoxy lacquered aluminium tubes containing 40 or 80 g of product closed with HDPE caps and presented in cardboard cartons.

Foil lined sachets containing 1g 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**

Mundipharma Pharmaceuticals Limited  
Millbank House  
Arkle Road  
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## **8 MARKETING AUTHORISATION NUMBER**

PA1688/021/006

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

Date of first authorisation: 01 April 1983

Date of last renewal: 01 April 2008

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

July 2019