

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Betadine Gargle and Mouthwash

Betasept Antiseptic Gargle and Mouthwash Concentrate

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Povidone Iodine USP 1.0% w/v (equivalent to 0.1% w/v of available iodine)

### **3 PHARMACEUTICAL FORM**

Oral Solution

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Betadine: For the treatment of Acute Mucosal Infections of the mouth and pharynx e.g. gingivitis, mouth ulcers, for oral hygiene prior to, during, and after dental and oral surgery.

Betasept: For the treatment of Acute Mucosal Infections of the mouth and pharynx e.g. gingivitis, mouth ulcers.

#### **4.2 Posology and method of administration**

Route of administration: Oral, as a gargle and mouthwash. The product should not be swallowed.

Adults, the elderly and children over 6 years of age: Use undiluted with an equal volume of warm water. Gargle or rinse with up to 10mls for up to 30 seconds without swallowing. Repeat up to four times daily, for up to 14 consecutive days, or as directed.

Not to be used in children of 6 years and under.

### **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). Regular use should be avoided in patients on concurrent lithium therapy. Do not use in children of 6 years and under.

### **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.

Do not use for more than 14 days.

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

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

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

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 stated.

#### **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 povidone 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 povidone 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**

Betadine Gargle & Mouthwash contains povidone-iodine, a complex of iodine which shows all the broad spectrum germicidal activity of povidone iodine. The germicidal activity is maintained in the presence of blood, pus, serum and necrotic tissue. Betadine Gargle and Mouthwash kills bacteria, viruses, fungi, spores and protozoa.

#### **5.2 Pharmacokinetic properties**

The product is intended for topical application to the mouth and buccal cavity.

### **5.3 Preclinical safety data**

None stated.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Glycerol
Menthol
Methyl Salicylate
Ethanol 96%
Saccharin Sodium
Purified Water

### **6.2 Incompatibilities**

None stated.

### **6.3 Shelf life**

36 Months unopened

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

Store in a dry place below 25°C. Protect from light.

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

Amber soda-lime-silica glass bottle (USP Type III), fitted with an externally ribbed white urea cap, with a steran faced wad or with a waddles polypropylene cap containing either 100ml, 150ml or 250ml of product.

### **6.6 Special precautions for disposal**

This product should not be swallowed.

**7      MARKETING AUTHORISATION HOLDER**

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**8      MARKETING AUTHORISATION NUMBER(S)**

PL 16431/0191

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

28<sup>th</sup> April 1993 / 19<sup>th</sup> November 1998

**10     DATE OF REVISION OF THE TEXT**

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