

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betadine 10 mg/ml Gargle and Mouthwash

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Iodinated Povidone 1% w/v (equivalent to 0.1% w/v of available iodine).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gargle, Mouthwash
Clear red-brown solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an antiseptic in the management of local infections of the mouth and oropharynx in dental surgery.

4.2 Posology and method of administration

Oral, as a gargle and mouthwash. The product should not be swallowed.

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 six 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. Regular use must be avoided as prolonged use may lead to the absorption of a significant amount of iodine particularly in patients with renal insufficiency. Do not use for more than 14 days. 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 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 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. The use of Betadine Gargle and mouthwash in pregnant and lactating women should be limited to a single treatment session only.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Idiosyncratic mucosal irritation and hypersensitivity reactions may occur.

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 is maintained in the presence of blood, pus, serum and necrotic tissue. Betadine Gargle & 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
Levomenthol
Methyl Salicylate
Ethanol 96%
Saccharin Sodium
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C. Protect from light.

6.5 Nature and contents of container

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

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

Use undiluted or diluted with an equal volume of warm water.

7 MARKETING AUTHORISATION HOLDER

Mundipharma Pharmaceuticals Limited
Millbank House
Arkle Road
Sandyford
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1688/021/005

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