

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betadine Alcoholic 100 mg/ml Cutaneous Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of cutaneous solution contains 100 mg of Iodinated Povidone (10% w/v).

This yields 10 mg/ml of available Iodine (1% w/v).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution

A dark brown coloured solution with an odour of alcohol.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an antiseptic for pre- and post-operative treatment of skin.

4.2 Posology and method of administration

For topical administration.

Apply directly as required.

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.

This preparation contains alcohol and is flammable. When used prior to a procedure which involves the use of an electrosurgical unit, do not allow pooling of the fluid to occur, and ensure that the skin and surrounding drapes are dry to reduce the risk of fires and burns.

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

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

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

Not relevant.

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

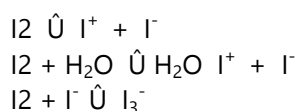
Deliberate or accidental ingestion of large quantities of povidone iodine will result in high blood concentrations of iodine and gastrointestinal corrosive effects including vomiting, diarrhoea and abdominal pain. Systemic toxicity may result in shock, hypotension, tachycardia, fever, metabolic acidosis 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

ATC code; D08AG02-Antiseptics and disinfectants

The active ingredient, Iodinated povidone slowly liberates iodine when in contact with skin and mucous membranes. The activity of iodine as a microbicide is then governed by a series of dissociations.



5.2 Pharmacokinetic properties

Betadine alcoholic solution is for topical application and therefore a consideration of the ADME of Iodinated povidone is largely without relevance.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Nonoxynol 9

Dibasic sodium phosphate (anhydrous)
Citric acid monohydrate
Industrial methylated spirit
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C. Store in the original package to protect from light.

6.5 Nature and contents of container

High density polyethylene containers with steran lined polypropylene caps.
Pack sizes: 500 ml and 5 litres.

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
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8 MARKETING AUTHORISATION NUMBER

PA1688/021/001

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