Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betadine 100 mg/ml Antiseptic Paint

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Iodinated Povidone 10% w/v (yielding 1.1% w/v available iodine).

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous solution
Glass bottle with applicator brush containing a brown coloured solution with an odour of alcohol.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a topical antiseptic in the prevention and treatment of topical cutaneous infections.

4.2 Posology and method of administration

For topical administration.

Apply to the affected area once or twice daily or as directed.

Apply directly to the affected area and allow to dry. Cover with a dressing if desired.

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. Allow to dry after use and avoid exposure to sources of ignition.

If local irritation and hypersensitivity develop, then discontinue treatment. Refer to section 4.8 for further information. Betadine Antiseptic Paint can permanently discolour white gold jewellery and it is recommended that this type of jewellery should be removed before using Betadine Antiseptic Paint.

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 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

Iodinated povidone is 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. It is effective in the treatment of infections caused by bacteria, fungi, yeasts and viruses (e.g. Herpes Virus Types I and II).

5.2 Pharmacokinetic properties

None stated.

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.

6.5 Nature and contents of container

Clear glass bottle with white polypropylene cap with an integral nylon application brush containing 8 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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Mundipharma Pharmaceuticals Limited
Millbank House
Arkle Road
Sandyford
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1688/021/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 15 March 2008

10 DATE OF REVISION OF THE TEXT

July 2019