Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betadine Mistette 10.0 % w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Povidone iodine 10.0% w/v.
Each ml contains 3 parts per million free iodine.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray solution
A reddish brown clear solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a topical antiseptic for the local management of minor skin trauma and the preparation of skin for surgical procedures.

4.2 Posology and method of administration

For topical use only.
Apply locally to affected area.

4.3 Contraindications

Use in patients with a known hypersensitivity to iodine. Use in children under 2 years of age. Use in patients with thyroid disorders.

4.4 Special warnings and precautions for use

Use of this preparation may interfere with tests of thyroid function. Special caution is needed when regular applications to broken skin are made in patients with pre-existing renal insufficiency. Regular use should be avoided in patients on concurrent lithium therapy. If used for prolonged periods, thyroid function tests should be performed.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Regular use should be avoided in pregnant or lactating women as absorbed iodine can cross the placental barrier and can be secreted in breast milk.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Local skin reactions can occur. Application to large wounds or severe burns, can produce systemic adverse effects such as metabolic acidosis, hypernatraemia and impairment of renal function.

4.9 Overdose

Due to the nature of this product, overdose is highly unlikely. However, excess iodine can produce goitre and hypothyroidism or hyperthyroidism. Systemic absorption of iodine after repeated applications of povidone iodine to large areas of wounds or burns may lead to a number of adverse effects: metallic taste in mouth, increased salivation, burning or pain in the throat or mouth, irritation, swelling of the eyes, pulmonary oedema, skin reactions, gastrointestinal upset and diarrhoea, metabolic acidosis, hypernatraemia, renal impairment. In the case of accidental ingestion of large quantities of Betadine, symptomatic and supportive treatment should be provided with special attention to electrolyte balance and renal and thyroid function.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Povidone iodine is a complex of iodine, which retains the broad spectrum germicidal activity of the elemental iodine without its disadvantages. The germicidal activity is maintained in the presence of blood, pus, serum and necrotic tissue. It is therefore suitable for use as a broad spectrum topical antiseptic for the prevention of infection in minor cuts, small areas of burns and treatment of bacterial skin infections and pyodermas, including infection i.e. decubitus and venous ulcers.

5.2 Pharmacokinetic properties

At the levels of iodine released fro the povidone iodine complex in this presentation, little systemic absorption would be expected.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Aqueous sodium hydroxide
Polyoxyethylene nonyl phenol alcohol
Phosphate buffer solution
Industrial methylated spirit
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

White PVC container fitted with a polyethylene actuator and a polyethylene dip tube, containing 100 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

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 1175/2/18

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 08 April 2002

10 DATE OF REVISION OF THE TEXT

February 2005