Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betadine Skin Cleanser 40mg/ml cutaneous solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 40 mg povidone iodine.

For excipients see Section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution.

Golden brown, clear viscous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the disinfection and cleansing of skin in the management of superficial infections.

4.2 Posology and method of administration

Apply to thoroughly wet skin, then rinse, twice daily or as directed by a physician.

4.3 Contraindications

Use in patients with hypersensitivity to iodine.

4.4 Special warnings and precautions for use

Use of the preparation may interfere with tests of thyroid function.
If there is aggravation of the condition or no improvement consult the doctor.

4.5 Interaction with other medicinal products and other forms of interactions

None stated.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Use of this preparation may interfere with tests of thyroid function.

4.9 Overdose

In the case of accidental ingestion of large quantities of Betadine, symptomatic and supportive treatment should be provided with special attention to electrolyte imbalance and renal and thyroid function.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D08AG02-Antiseptics and disinfectants
Betadine Skin Cleanser contains povidone-iodine, a complex of iodine which shows all the broad spectrum germicidal activity of elemental iodine.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium iodate
Sulphated nonoxynol
Lauric diethanolamide
Hydroxyethylcellulose
Perfume Vah Floral No. 2
Sodium hydroxide
Purified water

6.2 Incompatibilities

None stated.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original container.

6.5 Nature and contents of container

Polypropylene bottles with polypropylene screw caps containing 125 or 250ml of product.

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
Millbank House
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8 MARKETING AUTHORISATION NUMBER

PA1688/021/008

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th November 1975
Date of last renewal: 25th November 2005

10 DATE OF REVISION OF THE TEXT

July 2019