Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betadine Dry Powder 25 mg/g cutaneous spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of powder contains 25mg povidone-iodine

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, powder.

A reddish-brown powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Antiseptic for the treatment and prevention of infection in minor skin trauma including burns, cuts and other minor injuries.

4.2 Posology and method of administration

For topical use only.

Adults and children aged 2 years and older
Shake the can well before use. Spray the required area from a distance of 6-10 inches (15-25cm) until a dusting of powder is deposited. If necessary, the treated area may be covered with a dressing.
Not to be used in children under 2 years of age, see section 4.3.

4.3 Contraindications

Hypersensitivity to iodine, polyvinylpyrrolidone or any of the excipients. History of abnormal thyroid function or goitre (in particular nodular colloid goitre, endemic goitre and Hashimoto's thyroditis). Use in children under two years of age.
Regular use should be avoided in patients on concurrent lithium therapy. Avoid inhaling or spraying into eyes.
Betadine Dry Powder Spray should not be used in serous cavities.

4.4 Special warnings and precautions for use

If no improvement occurs a doctor should be consulted.
Use in the management of severe burns or denuded skin will lead to systemic absorption and may result in systemic effects such as metabolic acidosis, thyroid dysfunction or renal impairment.

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. In patients with impaired renal function, blood levels of iodine should be monitored.
If symptoms occur suggesting changes in thyroid function, these should be investigated.
If local irritation and hypersensitivity develop, then discontinue treatment. Refer to section 4.8 for further information.
Betadine Dry Powder Spray can permanently discolour white gold jewellery and it is recommended that this type of jewellery should be removed before using Betadine Dry Powder Spray.

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 have been reported or are known.

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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie.

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

D08AG02 - Antiseptics and disinfectants
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.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl Myristate
n-Pentane
Butane 40
Soya Lecithin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Store away from direct heat and sunlight.
Do not puncture, break or burn the can even if apparently empty.

6.5 Nature and contents of container

White printed, internally lacquered aluminium aerosol can. Pack size: 100ml.

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
Arkle Road
Sandyford
Dublin 18
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1688/021/004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th January 1986

Date of last renewal: 17th January 2006

10 DATE OF REVISION OF THE TEXT

July 2019