IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA1175/002/015
Case No: 2037610

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Transferred from PA0696/002/005.

Medlock Medical Ltd

Tubiton House, **Medlock Street**, **Oldham**, **OL1 3HS**, **England**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Betadine Antiseptic Tulle 250 mg Impregnated Dressing

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **08/06/2007**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Betadine Antiseptic Tulle 250 mg Impregnated Dressing

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dressing is impregnated with 2.5 g of gel containing 250 mg povidone iodine equivalent to 10% w/w.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Impregnated dressing.

10 x 10cm gauze dressing impregnated with a golden brown gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an antiseptic dressing for the management of cutaneous traumatic lesions and ulcers.

4.2 Posology and method of administration

For topical use only.

Apply as required to the affected area, cover with gauze or cotton wool and a bandage**.**

4.3 Contraindications

Hypersensitivity to iodine, polyvinylpyrrolidine 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 used for long periods thyroid function tests should be performed.

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

4.5 Interaction with other medicinal products and other forms of interaction

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 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 applicable.

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

Due to the nature of this product, overdose is highly unlikely. However, deliberate or accidental ingestion of large quantities of povidone iodine will result in high blood levels of iodine and gastrointestinal toxicity including vomiting and diarrhoea. Symptomatic and supportive treatment should be started with special attention to monitoring electrolyte balance, renal function, thyroid function and liver function. Iodine can be removed by dialysis.

5 PHARMACOLOGICAL PROPERTIES

D08AG02- Antiseptics and disinfectants

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 level of iodine released from 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

Macrogol 400
Macrogol 4000
Macrogol 6000
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

Each dressing is for single use only. Use immediately after opening.

6.4 Special precautions for storage

Do not store above 30 °C.

6.5 Nature and contents of container

Each 10 x 10cm gauze dressing is impregnated with at least 2.5 g of gel.
The dressing is placed between two polyethylene protective films and enclosed in a polyethylene/paper laminate sachet. Ten sachets are contained in an outer carton.

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

Medlock Medical Ltd
Tubiton House
Medlock Street
Oldham
OL1 3HS
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 1175/2/15

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th February 1992
Date of last renewal: 16th February 2007

10 DATE OF REVISION OF THE TEXT

June 2007