

**SUMMARY OF PRODUCT CHARACTERISTICS**

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### 1. NAME OF THE MEDICINAL PRODUCT

**Betadine Antiseptic Cream 5%**

Povidone-Iodine Cream

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

NAME OF INGREDIENT (S)	PHARMACOPOEIAL REFERENCE	QUANTITY (% w/w)
<b>ACTIVE INGREDIENT</b>		
Povidone Iodine (Assay at 10%)	USP	6.0*
<b>INACTIVE INGREDIENT(S)</b>		
Cetosteryl Alcohol	BP	10.0
Light Liquid Paraffin	BP	10.0
Glycerin	BP	5.0
Cremophor A6	IH	2.0
Cremophor A25	IH	2.0
Sodium Hydroxide	BP	0.125
Purified Water	BP	65.0

\*20% overages have been added to compensate the losses during the shelf life.

### 3. PHARMACEUTICAL FORM

Topical Cream

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

For the prevention of infection in burns, cuts, abrasions, poison ivy rash and insect bites. The treatment of skin infections, including infections of varicose & decubitus ulcers.

#### 4.2 Posology and method of administration

Route of administration: Topical.

Clean and dry the affected area, then apply the cream as prescribed. A dressing may be applied if required.

#### 4.3 Contraindications

Not to be used in known hypersensitivity to Iodine or Povidone. Not to be used in hyperfunction of the thyroid (hyperthyroidism), other manifest thyroid diseases, as well as before and after radioactive Iodine therapy. It should not be used prior to radio Iodine scintigraphy or radioiodine treatment of thyroid carcinoma.

#### 4.4 Special warnings and precautions for use

For topical use only. In instances of skin irritation or contact dermatitis or hypersensitivity, discontinue use. Do not heat prior to application. Keep out of the reach of children.

Patients with goiter, thyroid nodules, or other thyroid diseases are at risk of developing thyroid hyperfunction (hyperthyroidism) from the administration of large amounts of iodine. In this patient population, Povidone-iodine should not be applied for an extended period of time and to large areas of the skin unless strictly indicated. Even after the end of the treatment one should look for the early symptoms of possible hyperthyroidism and if necessary the thyroid function should be monitored.

Newborns and small infants are at increased risk of developing hypothyroidism from the administration of large amounts of iodine. Because of the permeable nature of their skin and the increased sensitivity to iodine, the use of povidone-iodine should be kept to the absolute minimum in newborns and small infants. A check of the child's thyroid function may be necessary. Any possible oral ingestion of povidone-iodine by the infant must be absolutely avoided. Blue stains on starched linen will wash off with soap and water.

Not for use in infections in children below 2 years of age.

#### 4.5 Interaction with other medicinal products and other forms of interaction

The PVP Iodine complex is effective at pH values between 2.0 and 7.0. It has to be expected that the complex will react with protein and other unsaturated organic compounds, leading to impairment of its effectiveness.

The concomitant use of wound treatment preparations containing enzymatic components leading to the weakening of the effects of both substances. Products containing mercury, silver, hydrogen peroxide, and taurolidine may interact with Povidone iodine and should not be used concomitantly.

#### 4.6 Pregnancy and lactation

During pregnancy and lactation, Povidone Iodine should only be used if strictly indicated and its use should be kept to the absolute minimum. Because of the ability of Iodine to pass through the

placenta and be secreted in breast milk, and because of the increased sensitivity of the foetus and new born to Iodine, no large amounts of Povidone Iodine should be administered during pregnancy and lactation. Povidone Iodine use may induce transient hypothyroidism with elevation of TSH in the foetus or in the new born. A check of the child's thyroid function may be necessary.

#### 4.7 Effects on ability to drive and use machines

None known.

#### 4.8 Undesirable effects

Undesirable effects occur rarely. Hypersensitive skin reactions may occur (e.g., delayed contact - allergic reactions, which can appear in the form of pruritis, erythema, small blisters or similar manifestations).

In single cases acute, generalized, allergic reactions, with drop in blood pressure and/or dyspnea (anaphylactic reactions) have been reported.

The long term use of povidone iodine solution for the treatment of wounds and burns over extensive areas of skin can lead to a notable uptake of Iodine. In isolated cases, patients with a history of thyroiddisease can develop hyperfunction of the thyroid (iodine induced hyperthyroisdism), sometimes with symptoms such as tachycardia or restlessness.

Following usage of large amounts of Povidone-Iodine (e.g., in the treatment of burns), the appearance of additional disorders of electrolyte imbalance and abnormal blood osmolarity, impairment of renal function with acute renal failure and metabolic acidosis have been described in the use of iodine-containing products.

#### 4.9 Overdose

Acute Iodine toxicity is manifested by abdominal symptoms, anuria, circulatory collapse, laryngeal edema resulting in asphyxia, or pulmonary edema and metabolic abnormalities.

Treatment is symptomatic and supportive.

## **5. PHARMACOLOGICAL PROPERTIES**

### 5.1 Pharmacodynamic properties

Betadine Antiseptic Cream is a topical microbicide active against organisms commonly encountered in skin and wound infections.

Betadine Antiseptic Cream may be used as an adjunct to systemic therapy where indicated; for primary or secondary topical infections, infected surgical incisions, infected decubitus or stasis ulcers, pyodermas, secondary infected dermatoses, and infected traumatic lesions.

Betadine Antiseptic Cream may be used to prevent microbial contamination in burns, incisions and other topical lesions; for degerming skin in hyperalimentation and catheter care. The use of Betadine antiseptic cream for abrasions, minor cuts, and wounds, may prevent the development of infections and permit wound healing.

Povidone-iodine is an iodophore, which is used as a disinfectant and antiseptic mainly for the treatment of contaminated wounds and pre-operative preparation of the skin and mucous membranes.

Iodophores are loose complexes of iodine and carrier polymers. Preparations of povidone-iodine gradually release iodine to exert an effect against bacteria, fungi, viruses, protozoa, cysts, and spores; povidone-iodine is thus less potent than preparations containing free iodine but it is less toxic.

Povidone-iodine retains the bactericidal activity of iodine but is less potent, therefore causes less irritation to skin and mucus membranes.

#### 5.2 Pharmacokinetic properties

The product is intended for topical application.

#### 5.3 Preclinical safety data

None stated.

### **6. PHARMACEUTICAL PARTICULARS**

#### 6.1 List of excipients

Cetosteryl Alcohol, Light Liquid Paraffin, Glycerin, Cremophor A6, Cremophor A25 & Sodium Hydroxide.

#### 6.2 Incompatibilities

None reported.

#### 6.3 Shelf life

24 months.

#### 6.4 Special precautions for storage

Store protected from light at a temperature not exceeding 30°C. Do not freeze.

#### 6.5 Nature and contents of container

PE Tube of 10 g and 20 g.

6.6 Special precautions for disposal and other handling

None stated.

**7. MARKETING AUTHORISATION HOLDER**

Modi-Mundipharma Private Ltd., New Delhi, India

**8. MARKETING AUTHORISATION NUMBER(S)**

Fresh registration

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Fresh registration

**10. DATE OF REVISION OF THE TEXT**

May, 2016