SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Betadine Ointment 5% w/w

(Povidone-Iodine Ointment USP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Formula :

Povidone-Iodine USP 5% w/w
(available Iodine 0.5% w/w)
Water soluble ointment base q.s

For full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Ointment for Topical application.

A dark brown, smooth ointment, free from any foreign matter and uniform in colour.

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 and decubitus ulcers.

4.2 Posology

For topical use only. The affected area is cleaned; the ointment is applied as prescribed. A dressing may be applied if required.

4.3 Method of administration

The product is intended for topical application.

4.4 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.

4.5 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 reach of children.

Patients with goiter, thyroid nodules, or other thyroid diseases are at risk of developing thyroid hyperfunction (hyperthyroidism) from the application of large amount of Iodine. In this patient population, Povidone iodine ointment should not be applied for an extended period of time and to large areas of 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. Due to 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.

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

4.6 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.

4.7 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. Any possible oral ingestion of the solution by the infant must be absolutely avoided.

4.8 Effects on ability to drive and use machines

None known.

4.9 Undesirable effects

Hypersensitive skin reactions may occur (e.g., delayed contact -allergic reactions, which can appear in the form of pruritus, 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 ointment 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 thyroid disease can develop hyperfunction of the thyroid (iodine induced hyperthyroisdism), sometimes with symptoms such as tachycardia or restlessness.

Following uptake 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 if iodine containing products.

4.10 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 Ointment is a topical microbicide active against organisms commonly encountered in skin and wound infections. Betadine ointment may be used as an adjunct to systemic therapy where indicated; for primary or secondary topical infections, infected surgical incisions and other topical lesions; for degerming skin; in hyperalimentation and catheter care. The use of Betadine Ointment 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 preparations 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, virus, protozoa, cysts and spores. Povidone Iodine is thus less potent than preparations containing free iodine but is less toxic. Povidone Iodine retains the bactericidal activity of iodine but is less potent, therefore causes less irritation to skin and mucous 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

1. Polyethylene Glycol 400
2. Polyethylene Glycol 3350
3. Sodium Bicarbonate.
4. Purified water

6.2 Incompatibilities

None reported.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 30^{o}C. Do not freeze. Replace the cap tightly after use.

6.5 Nature and contents of container

1. Aluminum Collapsible Tube of 15 ml enclosed in a carton with pack insert
2. Aluminum Collapsible Tube of 125 ml enclosed in a carton with pack insert
3. HDPE Jar of 250 g.

6.6 Special precautions for disposal and other handling

None stated.

7. MARKETING AUTHORISATION HOLDER

Modi-Mundipharma Private Ltd., 1400, Modi Tower, 98, Nehru Place, New Delhi 110019, India

8. MARKETING AUTHORISATION NUMBER(S)

Rwanda FDA-HMP-MA-1365

9. DATE OF FIRST AUTHORISATION

29-02-2024

10. DATE OF REVISION OF THE TEXT

28-05-2024