SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Betadine Standardized Microbicidal Solution 10% w/v

(Povidone-Iodine Topical Solution USP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Formula:

Povidone-Iodine USP 10% w/v
(available Iodine 1.0 %w/v)
Purified water q.s.

For full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Solution for Topical application.

A clear dark brown liquid free from foreign matter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Disinfection of wounds, lacerations, abrasion, and burns. Prophylaxis against infection in hospital and surgery procedure. Preparation of skin and in mucous membranes prior to surgery. Post operative application to protect against infection. Treatment of infected skin conditions.

4.2 Posology

For topical use only. Apply full strength as often as needed as a pain or wet soak. Allow to dry before applying surgical drapes and avoid 'pooling' beneath the patient. Prolonged exposure to the solution may cause irritation or rarely severe skin reaction. In rare instance of local irritation or sensitivity, discontinue use.

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

Prolonged exposure to wet solution may cause irritation or rarely, severe skin reactions. Chemical burns of skin due to “pooling” may occur. 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 administration of large amount of Iodine. In this patient population, Povidone iodine solution 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.

New-born and small infants are at increased risk of developing hypothyroidism from the administration of large amounts of Iodine. 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.

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

Rarely. 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 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 thyroid disease can develop hyperfunction of the thyroid (iodine induced hyperthyroidism), 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 Standardized Microbicidal Solution has a rapid and prolonged germicidal activities action against a wide spectrum of pathogenic organisms including gram positive and gram negative bacteria, fungi, protozoa and virus. It is also active against bacterial spores. In the presence of blood, serum, purulent exudates and necrotic tissues.

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. Citric Acid Monohydrate
2. Dibasic Sodium Phosphate
3. Glycerin
4. Hydroxy AAO/Alphox -200
5. Potassium Iodate
6. Sodium Hydroxide
7. Purified Water

6.2 Incompatibilities

None reported.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at a temperature below 30^{o}C, protected from light and moisture. Replace the cap tightly after use.

6.5 Nature and contents of container

1. Amber PET bottle of 50 ml enclosed in a carton with a pack insert.
2. Amber PET bottle of 100 ml enclosed in a carton with a pack insert.
3. Brown HDPE bottle of 500 ml.

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-1381

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29-02-2024

10. DATE OF REVISION OF THE TEXT

28-05-2024