SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Betadine Germicide Gargle 2%-Mint

(Povidone-Iodine Gargle)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Formula :

Povidone-Iodine USP 2% w/v
(available iodine 0.2% w/v)
Absolute Alcohol content 8.38% v/v
In a mint flavour aqueous base

For full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Solution (Gargle) for oropharyngeal administration. A clear dark brown liquid with characteristic odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As a mouth wash for routine use. Eliminates or reduces offensive mouth odors. As a gargle or mouth wash as primary or adjunctive therapy in infections of the mouth and throat such as aphthous ulcers, stomatitis, Vincent's infection, pharyngitis, oral moniliasis tonsillitis and following oral surgery and dental procedures.

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

4.2 Posology

Posology:

Adults & Children : Dilute Betadine Germicide Gargle 2% Mint with an equal volume of water and gargle or rinse for 30 seconds. Repeat every two to four hours for as long as required.

For gargle or mouth wash:
Dilute Betadine Germicide Gargle 2% Mint with an equal volume of water and rinse or gargle for 30 seconds and then spit out, repeat hourly or as directed by physician.

As a routine mouthwash : Effective up to dilution of one part Betadine Germicide Gargle 2% Mint with two parts of water, rinse mouth thoroughly & spit out, or as directed by physician or dentist.

4.3 Method of administration:

The product is intended for oropharyngeal administration. For external use only.

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 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. 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 newborn 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 newborn. 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 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 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.

4.10 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

Pharmacotherapeutic group: Antiseptics and Disinfectants, ATC code: D08AG02

High dilutions are active in destroying, within fifteen seconds, the organisms commonly found in the mouth. It is effective in higher dilutions than the stock commercial preparations of the other common antiseptics studied. Povidone-iodine is extremely effective as a germicide on the oral flora and that it can be used as such in high dilutions. 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. Solutions 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 mucous membranes.

5.2 Pharmacokinetic properties

The product is intended for application to the mouth and the buccal cavity.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerin, Menthol, Methyl Salicylate, Sodium Saccharin, Alcohol 95 % v/v

6.2 Incompatibilities

None reported.

6.3 Shelf life

18 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30^0C, protected from light and moisture.

6.5 Nature and contents of container

Betadine Germicide Gargle 2% is supplied as Amber PET Bottle of 50 ml and 100 ml, enclosed in a caron along with pack insert.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT

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

8. FDA REGISTRAITON NUMBER

Rwanda FDA-HMP-MA-1382

9. DATE OF FIRST AUTHORIZATION

May-2024

10. DATE OF REVISION OF THE TEXT

28-05-2024