1.6.3
Patient information leaflet (PIL)

1.6.3 Patient Information leaflet

Package Insert of Betadine Standardised Microbicidal Solution 5% is enclosed.

Pack Size: Betadine™ Standardised Microbicidal Solution is supplied in Amber coloured pet bottle of 50 ml, 100 ml fitted with HDPE caps and in 500 ml HDPE bottle.

Manufactured by :
G.S. Pharmbutor Pvt. Ltd.,
B-172, Industrial Area, Behror – 301 701,
Rajasthan, India.

TM : Trade Mark

PPI027 Ed.I / 01.16

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Povidone-Iodine Topical Solution USP 5% w/v

Betadine™

Standardised Microbicidal Solution

DESCRIPTION

Povidone-Iodine is iodine complexed with povidone (polyvinyl-pyrrolidone). It is yellowish brown to reddish brown amorphous powder. Its chemical name is 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compound with iodine.

Povidone Iodine is soluble in water and ethanol (95%), and practically insoluble in chloroform, acetone and ether.

Betadine™ Standardised Microbicidal Solution is supplied as clear dark brown coloured liquid with pH 3.0–6.50

Formula:

Povidone-Iodine USP	5% w/v
(available iodine	0.5% w/v)
Purified water	q.s

INDICATIONS AND USAGE

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.

PHARMACOLOGY

Pharmacodynamics/ Pharmacokinetics

Povidone-Iodine topical solution is intended for topical application. Povidone-Iodine retains the bactericidal activity of iodine but is less potent, therefore causes less irritation to skin and mucous membranes. In-vitro HIV appears to be completely inactivated by Povidone-Iodine preparations.

Betadine™ Standardised Microbicidal Solution has a rapid and prolonged germicidal action against a wide spectrum of pathogenic organisms including both Gram-positive and Gram-negative bacteria, fungi, protozoa and viruses. It is also active against bacterial spores. In the presence of blood, serum, purulent exudates and necrotic tissue, it's activity persists as long as the colour remains. The golden brown colour serves to highlight the disinfected areas.

Povidone-Iodine topical solution is used as a general topical bactericide/virucide for disinfection of wounds, emergency treatment of lacerations and abrasions; second and third-degree burns, as a prophylactic anti-infective agent in hospital and office procedures, including post-operative applications to incisions to help prevent infection, bacterial and mycotic skin infections, decubitus and stasis ulcers, as a pre-operative swab.

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

Carton A/w of **Betadine Standardised Microbicidal Solution 5% - PI**
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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.

DOSAGE AND ADMINISTRATION

Apply full strength as often as needed as a paint 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.

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 radioiodine scintigraphy or radioiodine treatment of thyroid carcinoma.

WARNING AND PRECAUTIONS

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 solution 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.

CAUTION- If local irritation or sensitivity develop then discontinue use. If no improvement occurs, please consult your doctor.

INTERACTIONS

The PVP-iodine complex is effective at pH values of 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 leads to 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.

Note: Due to the oxidative effect of Povidone-Iodine solution various diagnostic agents can show false-positive lab results (e.g. tests with toluidine or gum guaiac for the determination of hemoglobin or glucose in the stool or the urine).

Absorption of iodine from Povidone-Iodine solution may interfere with thyroid function tests. During the use of Povidone-Iodine solution the iodine uptake of the thyroid can be lowered; this can lead to interference with various investigations (thyroid scintigraphy, determination of PBI [protein-bound iodine], radioiodine diagnostics) and can make a planned treatment of the thyroid with iodine (radioiodine therapy) impossible after the end of the treatment, an appropriate interval should be allowed before a new scintigram is carried out.

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.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

It has no effect on the person's ability to drive and perform potentially hazardous tasks such as operating machinery.

ADVERSE REACTIONS

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 the 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 of iodine-containing products.

OVERDOSAGE & TREATMENT

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.

PHARMACEUTICAL PARTICULARS

Incompatibilities: None Reported

Shelf Life: 24 months from the date of manufacturing.

Storage precautions: Store protected from light at a temperature not exceeding 30°C. Replace the cap tightly after use.

Keep all medicines out of reach of children.

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