SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Betadine Surgical Scrub7.5% w/w

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

NAME OF INGREDIENTS	Reference Standard	Quantity (% w/v)	Function	Label Claim
ACTIVE				
Povidone Iodine (Assay at 10% available Iodine)	USP	9.0*	Active	7.5 % w/v
INACTIVE INGREDIENT(S)				
Hyoxyd-X-301/IG Surf 4301/Tabonic SE 305(30% solids)	IH	46.50	Surfactant	
Superamide	IH	2.40	Surfactant	
Sodium Hydroxide	BP	0.15	Alkalizing agent	
Purified Water (%v/v) q.s. to	BP	100	Vehicle	

*Contains 20% overages to compensate for the loss during storage at shelf life.

3. PHARMACEUTICAL FORM

Cleansing Solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the Pre and postoperative scrubbing or washing, pre and postoperative use on patients, general use in physician's office.

4.2 Posology and method of administration

Route of administration: Topical

A. For Preoperative Washing by operating Personnel

B. For Preoperative Use on Patients

C. Use in physician clinic

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 radioiodine scintigraphy or radioiodine treatment of thyroid carcinoma.

4.4 Special warnings and precautions for use

For topical use only. In pre-operative preparation, avoid "pooling" beneath the patient. Prolonged exposure to wet scrub may cause irritation or rarely, severe skin reactions. In instances of skin irritation or contact dermatitis or hypersensitivity, discontinue use. Keep out of the reach of children. Preparations containing povidone-iodine may permanently stain rhodium-plated white gold. They may also temporarily discolour some precious metals in which case any discoloration can readily be removed with an appropriate metal polish or non-abrasive cleaner.

Patients with goiter, thyroid nodules, or other thyroid diseases are at risk of developing thyroid hyperfunction (hyperthyroidism) from the usage 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.

4.5 Interaction with other medicinal products and other forms of interaction

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.

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 fetus and newborn to iodine, no large amounts of povidone-iodine should be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

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 (analphylctic reactions) have been reported.

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 Surgical scrub has a rapid and prolonged germicidal action against a wide spectrum of pathogenic organisms including both Gram-positive and Gramnegative 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. A broad spectrum antiseptic, bactericidal, virucidal sudsing skin cleanser for pre-and-postoperative scrubbing or washing by hospital operating room personnel; for preoperative use on patients; and general use as an antiseptic microbicide in physician's office. Forms rich, golden lather.

Povidone-iodine surgical scrub is intended for topical application.

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. In-vitro HIV appears to be completely inactivated by Povidone-iodine preparations.

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

Tabonic SE 305

Superamide

Sodium Hydroxide

Purified water

6.2 Incompatibilities

None reported.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

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

Replace the cap tightly after use.

6.5 Nature and contents of container

Betadine Surgical Scrub 7.5% w/v is supplied as Amber PET Bottle of 50 ml and Brown HDPE bottle of 500 ml.

6.6 Special precautions for disposal and other handling

None stated.

7. MARKETING AUTHORISATION HOLDER

Modi-Mundipharma Private Limited, 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

March, 2016.