1.3
PRODUCT INFORMATION

1.3 PRODUCT INFORMATION

1.3.1 Summary of products characteristics (SPC)

Summary of Product characteristics of Betadine Standardised Microbicidal Solution 5% is enclosed.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Betadine Standardized Microbicidal Solution 5% w/v

Povidone-Iodine Topical Solution USP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

NAME OF INGREDIENTS	Reference Standard	Quantity (% w/v)
ACTIVE INGREDIENT Povidone Iodine (Assay at 10%)	USP	5.0
INACTIVE INGREDIENT(S)		
Citric Acid Monohydrate	BP	0.42
Dibasic Sodium Phosphate	USP	0.75
Glycerine	BP	1.0
Hydroxy AAO/Alphox -200	IH	0.25
Potassium Iodate	BP	0.03
Sodium Hydroxide	BP	0.0125
Purified Water (%v/v) q.s. to	BP	100

3. PHARMACEUTICAL FORM

Aqueous Topical Solution.

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 and method of administration

Route of administration: Topical. 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 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.

4.4 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.

4.5 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.

4.6 Pregnancy and lactation

During pregnancy and lactation, Povidone Iodine should only be used if strictly indicated and its use should be kept to he 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.

4.7 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 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 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.

4.9 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 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

Citric Acid Monohydrate, Dibasic Sodium Phosphate, Glycerine, Hydroxy AAO/Alphox -200, Potassium Iodate, Sodium Hydroxide, 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

Amber Glass bottle of 50 ml and 100 ml, 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., 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

December 2019.

1.3.2 Container labelling

Artworks of Carton and Label of Betadine Standardised Microbicidal Solution 5% are enclosed.

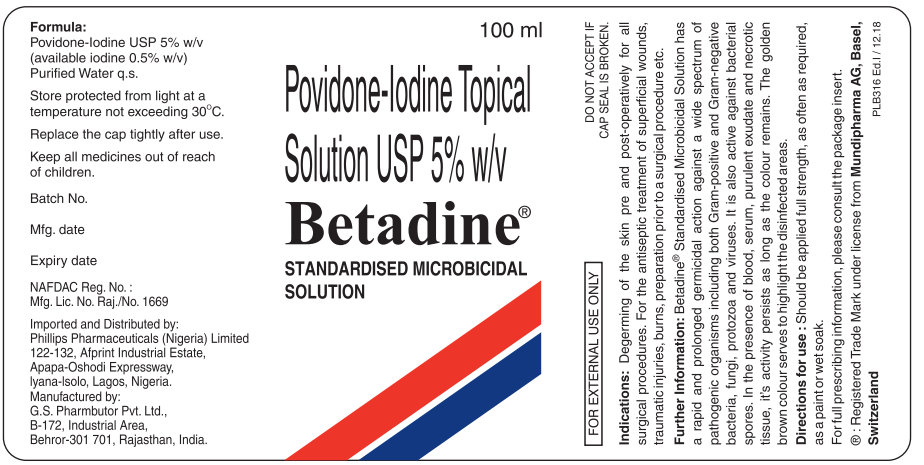
Pantone 281C
Pantone 485C
Black

Artwork of
Betadine Solution 5% 50ml Label
Size : 105 x 40mm, Same Size Artwork,
12.12.2018, Dynamic Design (OD1218)

150%

Pantone 281C
Pantone 485C
Black

Artwork of **Betadine Solution 5% 50ml**
Artwork size : 39 x 39 x 98 mm, Same Size Artwork,
12.12.2018, Dynamic Design (OD1218)



Pantone 281C
Pantone 485C
Black

Artwork of
Betadine Standardised Microbicidal Solution 100ml Label
Artwork size : 120 x 60 mm, Same Size Artwork,
12.12.2018, Dynamic Design (OD1218)

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

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.

Batch No.

Mfg. date

Expiry date

NAFDAC Reg. No. :
Mfg. Lic. No. Raj./No. 1669

Imported and Distributed by:
Phillips Pharmaceuticals (Nigeria) Limited
122-132, Afprint Industrial Estate,
Apapa-Oshodi Expressway,
Iyana-Isolo, Lagos, Nigeria.
Manufactured by:
G.S. Pharmbutor Pvt. Ltd.,
B-172, Industrial Area,
Behror-301 701, Rajasthan, India.

100 ml

Povidone-Iodine Topical Solution USP 5% w/v

Betadine®

STANDARDISED MICROBICIDAL SOLUTION

DO NOT ACCEPT IF CAP SEAL IS BROKEN.

FOR EXTERNAL USE ONLY

Indications: Degerming of the skin pre and post-operatively for all surgical procedures. For the antiseptic treatment of superficial wounds, traumatic injuries, burns, preparation prior to a surgical procedure etc.

Further Information: 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 exudate and necrotic tissue, it's activity persists as long as the colour remains. The golden brown colour serves to highlight the disinfected areas.

Directions for use : Should be applied full strength, as often as required, as a paint or wet soak.

For full prescribing information, please consult the package insert.

®: Registered Trade Mark under license from **Mundipharma AG, Basel, Switzerland**

PLB316 Ed.I / 12.18

150%

Pantone 281C
Pantone 485C
Black

Artwork of **Betadine Solution 100ml**
Artwork size : 45 x 45 x 123 mm, Same Size Artwork,
12.12.2018, Dynamic Design (OD1218)

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

Batch No.

Mfg. date

Expiry date

FOR EXTERNAL USE ONLY

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.

NAFDAC Reg. No. :
Mfg. Lic. No. Raj./No. 1669

Imported and Distributed by:
Phillips Pharmaceuticals (Nigeria) Limited
122-132, Afprint Industrial Estate,
Apapa-Oshodi Expressway,
Iyana-Isolo, Lagos, Nigeria.
Manufactured by:
G.S. Pharmbutor Pvt. Ltd.,
B-172, Industrial Area,
Behror-301 701, Rajasthan, India.

8 901814 002971

500 ml

Povidone-Iodine Topical Solution USP 5% w/v

Betadine®

STANDARDISED MICROBICIDAL SOLUTION

DO NOT ACCEPT IF CAP SEAL IS BROKEN.

Indications: Degerming of the skin pre and post-operatively for all surgical procedures. For the antiseptic treatment of superficial wounds, traumatic injuries, burns, preparation prior to a surgical procedure etc.

Further Information: 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 exudate and necrotic tissue, it's activity persists as long as the colour remains. The golden brown colour serves to highlight the disinfected areas.

Directions for use : Should be applied full strength, as often as required, as a paint or wet soak.

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PLB317 Ed.I / 12.18

Pantone 281C
Pantone 485C
Pantone Cool Gray 11 C

Artwork of
Betadine Standardised Microbicidal Solution 500ml Label
Artwork size : 160 x 90 mm,
12.12.2018, Dynamic Design (OD1218)

1.3.3 Patient Information leaflet

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

Pack Size: Betadine® Standardised Microbicidal Solution 5% is supplied in Amber coloured pet bottle of 50 ml, 100 ml fitted with HDPE caps and in 500 ml HDPE bottle.

NAFDAC Reg. No. :
Mfg. Lic. No. Raj./No. 1669

Imported and Distributed by:
Phillips Pharmaceuticals (Nigeria) Limited
122-132, Afprint Industrial Estate,
Apapa-Oshodi Expressway,
Iyana-Isolo, Lagos, Nigeria.

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

® : Registered Trade Mark under license from
Mundipharma AG, Basel, Switzerland

PPI080 Ed.I / 12.18

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 5%

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 5% 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 5% 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.

Carton A/w of **Betadine Standardised Microbicidal Solution 5% - PI (Nigeria)**
Actual Size : 70+70 x 210 mm Same Size Print Out
20.12.2018 / **Dynamic Design**(OD1218)

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.

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.

Carton A/w of **Betadine Standardised Microbicidal Solution 5% - PI (Nigeria)**
Actual Size : 70+70 x 210 mm Same Size Print Out
20.12.2018 / **Dynamic Design**(OD1218)