1.3
PRODUCT INFORMATION

1.3 PRODUCT INFORMATION

1.3.1 Summary of products characteristics (SPC)

Summary of Product characteristics of Betadine Antiseptic Cream 5% is enclosed.

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Betadine Antiseptic Cream 5%

Povidone-Iodine Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

NAME OF INGREDIENT (S)	PHARMACOPOEIAL REFERENCE	QUANTITY (% w/w)
ACTIVE INGREDIENT		
Povidone Iodine (Assay at 10%)	USP	6.0*****
INACTIVE INGREDIENT(S)		
Cetosteryl Alcohol	BP	10.0
Light Liquid Parrafin	BP	10.0
Glycerin	BP	5.0
Cremophor A6	IH	2.0
Cremophor A25	IH	2.0
Sodium Hydroxide	BP	0.125
Purified Water	BP	65.0

*****20% overages have been added to compensate the losses during the shelf life.

3. PHARMACEUTICAL FORM

Topical Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the prevention of infection in burns, cuts, abrasions, poison ivy rash and insect bites. The treatment of skin infections, including infections of varicose & decubitus ulcers.

4.2 Posology and method of administration
Route of administration: Topical.

Clean and dry the affected area, then apply the cream as prescribed. A dressing may be applied if required.

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

For topical use only. In instances of skin irritation or contact dermatitis or hypersensitivity, discontinue use. 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. Because of the permeable nature of their skin and the increased sensitivity to iodine, the use of povidone-iodine should be kept to the absolute minimum in newborns and small infants. 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. Blue stains on starched linen will wash off with soap and water.

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

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 be 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.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Undesirable effects occur 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 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.

4.9 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 Antiseptic Cream is a topical microbicide active against organisms commonly encountered in skin and wound infections.

Betadine Antiseptic Cream may be used as an adjunct to systemic therapy where indicated; for primary or secondary topical infections, infected surgical incisions, infected decubitus or stasis ulcers, pyodermas, secondary infected dermatoses, and infected traumatic lesions.

Betadine Antiseptic Cream may be used to prevent microbial contamination in burns, incisions and other topical lesions; for degerming skin in hyperalimentation and catheter care. The use of Betadine antiseptic cream for abrasions, minor cuts, and wounds, may prevent the development of infections and permit wound healing.

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. Preparations 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 mucus membranes.

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

Cetosteryl Alcohol, Light Liquid Paraffin, Glycerin, Cremophor A6, Cremophor A25 & Sodium Hydroxide.

6.2 Incompatibilities

None reported.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at a temperature below 30^0C, protected from light and moisture.

6.5 Nature and contents of container

PE Tube of 10 g and 20 g.

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

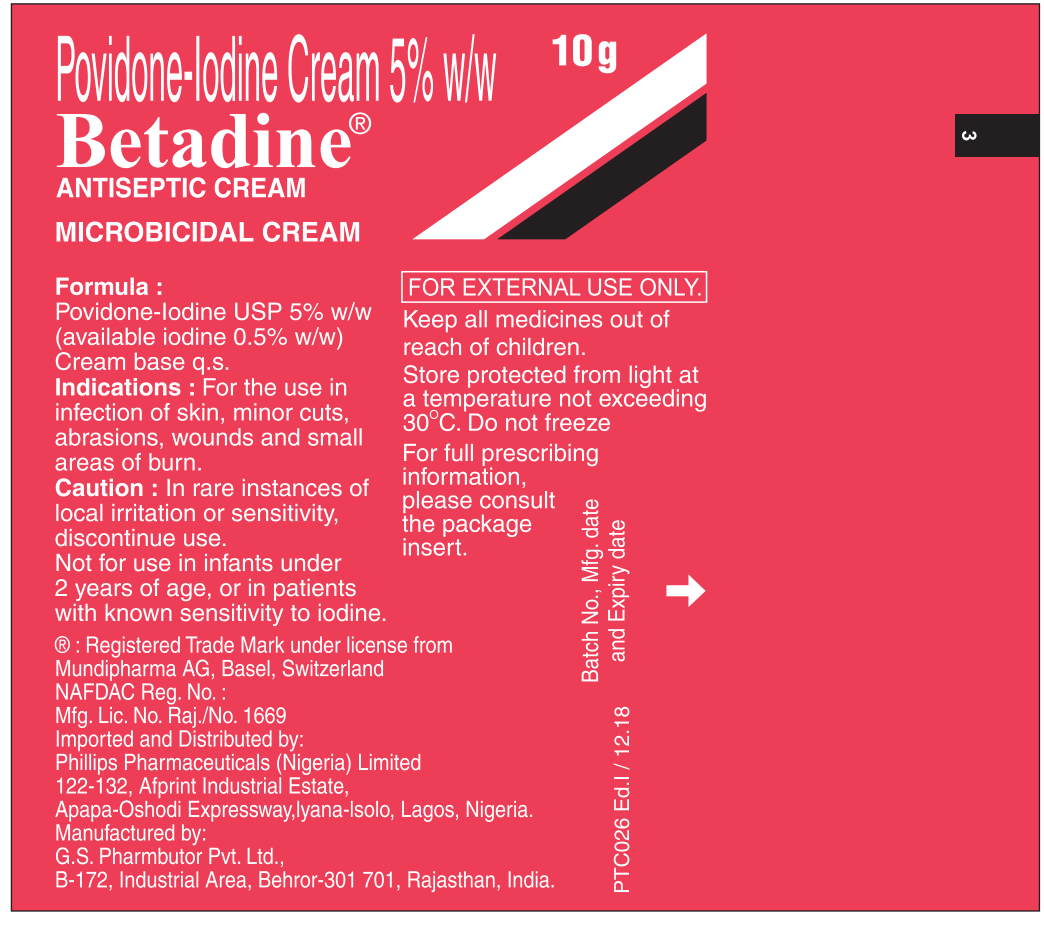
December 2019.

1.3.2 Container labelling

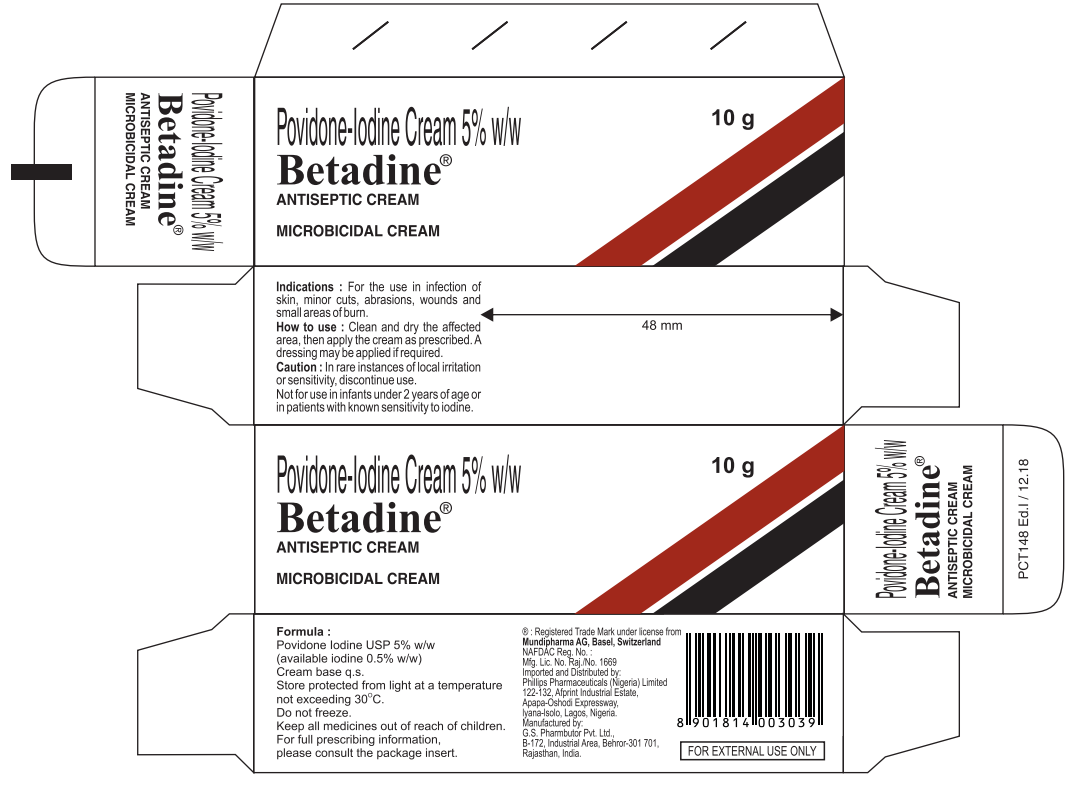
Artworks of Carton and Label of Betadine Antiseptic Cream 5% are enclosed.

Artwork of **Betadine Antiseptic Cream Tube 10 g**,
Size - 68 x 60 mm, Same Size Artwork,
12.12.2018, Dynamic Design (OD1218)

- Black
- PANTONE Red 032 C
- White



200%



Black
Pantone 484 C

Artwork of **Betadine Cream - 10g Carton**
Artwork size : 78 x 21 x 25 mm, Same Size Artwork,
12.12.2018, Dynamic Design (OD1218)

A/w size : 200% enlarged

Povidone-Iodine Cream 5% w/w

20g

Betadine®

ANTISEPTIC CREAM

MICROBICIDAL CREAM

3

Formula :
Povidone-Iodine USP 5% w/w
(available iodine 0.5% w/w)
Cream base q.s.

Indications : For the use in infection of skin, minor cuts, abrasions, wounds and small areas of burn.

Caution : In rare instances of local irritation or sensitivity, discontinue use.
Not for use in infants under 2 years of age, or in patients with known sensitivity to iodine.

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

FOR EXTERNAL USE ONLY.

Keep all medicines out of reach of children.
Store protected from light at a temperature not exceeding 30°C. Do not freeze

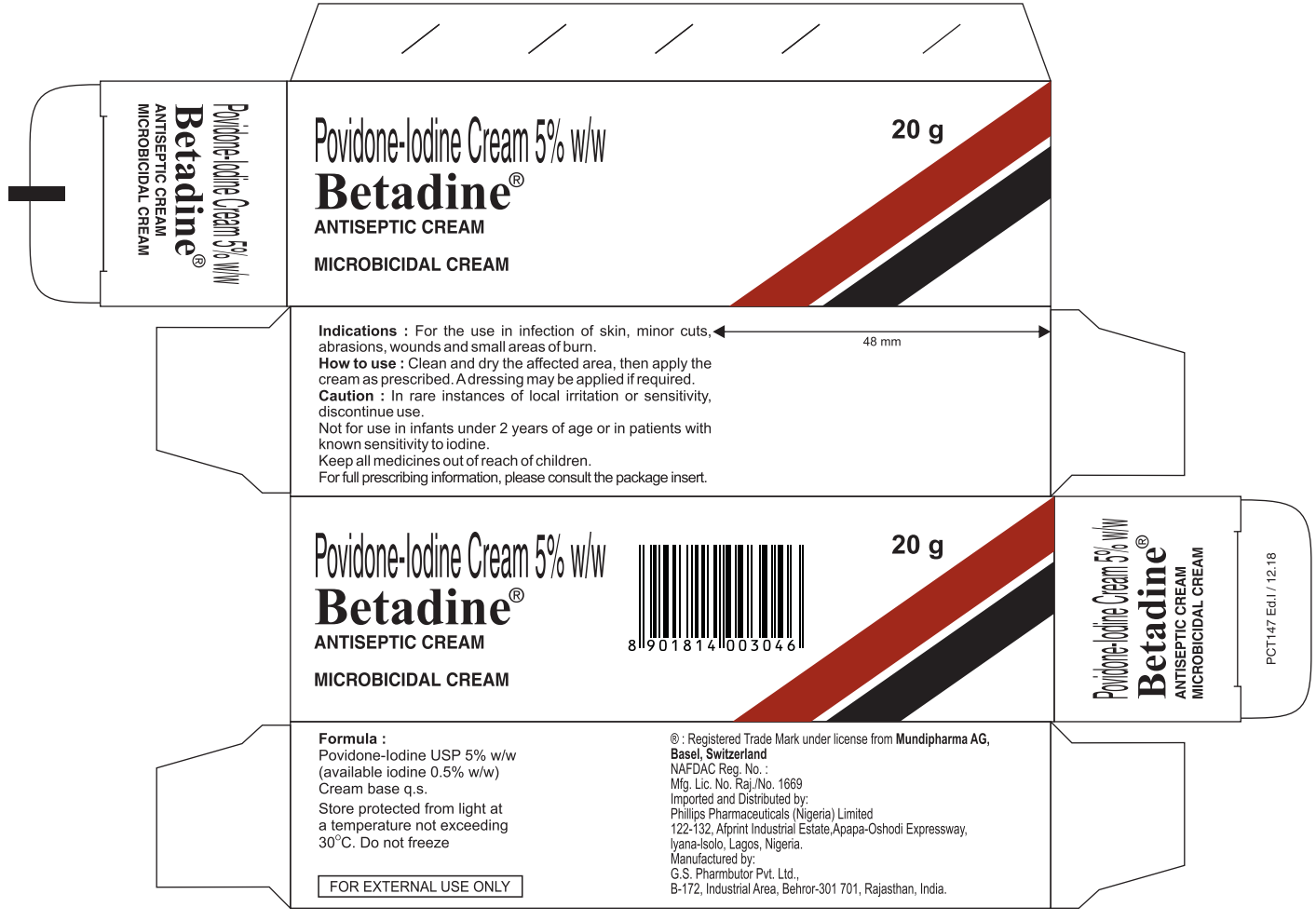
For full prescribing information, please consult the package insert.

Batch No., Mfg. date and Expiry date

PTC025 Ed.I / 12.18

Black
PANTONE Red 032 C
White

Artwork of **Betadine Antiseptic Cream Tube 20 g**,
Actual Size - 90 x 80 mm, Artwork 2 times enlarged,
12.12.2018, Dynamic Design (OD1218)



Black
Pantone 484 C

Artwork of **Betadine Cream - 20g Carton**
Artwork size : 108 x 32 x 27 mm, Same Size Artwork,
12.12.2018, Dynamic Design (OD1218)

1.3.3 Patient Information leaflet

Package insert of Betadine Antiseptic Cream 5% is enclosed.

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

Povidone-Iodine Cream 5% w/w

Betadine®

Antiseptic Cream

Microbicidal Cream

DESCRIPTION

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

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

Betadine® Antiseptic Cream is supplied as brown smooth cream, free from foreign matter.
Formula:
Povidone-Iodine USP 5% w/w
(available iodine 0.5% w/w)
Cream base q.s

INDICATIONS AND USAGE

For the prevention of infection in burns, cuts, abrasions, poison ivy rash and insect bites. The treatment of skin infections, including infections of varicose & decubitus ulcers.

PHARMACOLOGY

Pharmacodynamics/ Pharmacokinetics

Betadine® antiseptic cream is a topical microbicide active against organisms commonly encountered in skin and wound infections.

Betadine® antiseptic cream may be used as an adjunct to systemic therapy where indicated; for primary or secondary topical infections, infected surgical incisions, infected decubitus or stasis ulcers, pyodermas, secondary infected dermatoses, and infected traumatic lesions.

Betadine® antiseptic cream may be used to prevent microbial contamination in burns, incisions and other topical lesions; for degerming skin in hyperalimentation and catheter care. The use of Betadine® antiseptic cream for abrasions, minor cuts, and wounds, may prevent the development of infections and permit wound healing.

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. Preparations 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 mucus membranes.

A/w of **Betadine Cream 5% - PI (Nigeria)**
Actual Size : 70+70 x 210 mm Same Size Print Out
24.12.2018/ **Dynamic Design** (OD1218)

DOSAGE AND ADMINISTRATION

FOR EXTERNAL USE ONLY

Clean and dry the affected area, then apply the cream as prescribed. A dressing may be applied if required.

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

For topical use only. In instances of skin irritation or contact dermatitis or hypersensitivity, discontinue use. 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 application of large amounts of iodine. In this patient population, Povidone-Iodine cream 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. Because of the permeable nature of their skin and the increased sensitivity to iodine, the use of Povidone-Iodine should be kept to the absolute minimum in newborns and small infants. 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.

Blue stains on starched linen will wash off with soap and water.

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

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 it's 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, 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 cream may interfere with thyroid function tests. During the use of Povidone-Iodine preparations 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 it's 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.

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 preparations 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 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.

OVERDOSAGE & TREATMENT

Acute iodine toxicity is manifested by abdominal symptoms, anuria, circulatory collapse, laryngeal oedema resulting in asphyxia, or pulmonary edema and metabolic abnormalities.

Treatment is symptomatic and supportive.

PHARMACEUTICAL PARTICULARS

Incompatibilities: None Reported

Shelf Life: 24 Months

Storage precautions: Store protected from light at a temperature not exceeding 30°C. Do not freeze.

Replace the cap tightly after use.

Presentation: 10 g and 20 g tube.

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.

PPI083 Ed.I / 12.18

A/w of **Betadine Cream 5% - PI (Nigeria)**
Actual Size : 70+70 x 210 mm Same Size Print Out
24.12.2018/ **Dynamic Design** (OD1218)