

## BETADINE® ANTISEPTIC SOLUTION

*Mundipharma Middle East FZ LLC*

Active substance: Povidone-iodine (PVP-iodine)  
10% w/v  
Topical antiseptic

### 1- What is BETADINE® Antiseptic Solution and what is that used for?

#### What is BETADINE® Antiseptic Solution?

BETADINE® Antiseptic Solution is the original aqueous solution of Povidone-iodine, for use as an antiseptic on the skin, mucous membranes and wounds.

#### What does BETADINE® Antiseptic Solution contain?

- Active substance : Povidone-iodine 10% w/v
- Inactive ingredients: glycerol, nonoxinol 9, potassium iodate, dibasic sodium phosphate, citric acid, sodium hydroxide, purified water.

#### What is BETADINE® Antiseptic Solution used for?

BETADINE® Antiseptic Solution is indicated for degerming skin, wounds and mucous membranes in:

- Preoperative preparation of skin and mucous membranes.
- Post-operative surgical wound infection.
- Casualty procedures, including prevention of infection in burns, lacerations and abrasions.
- Treatment of various bacterial, viral, protozoal and mycotic skin infections, including tinea, oral thrush, impetigo and herpes simplex and zoster infections.
- For hygienic and surgical disinfection of the hands.

#### 2- Packing sizes:

BETADINE® Antiseptic Solution is an iodine coloured solution supplied in High-density polyethylene containers fitted with inserts from low-density polyethylene and polypropylene caps.

BETADINE® Antiseptic Solution is available in packs of 30 ml, 120 ml, 125 ml, 500 ml, 1000 ml and 5000 ml.

Not all the pack sizes may be marketed.

### 3- Before using BETADINE® Antiseptic Solution:

#### Contraindications:

- Not to be used in known or suspected hypersensitivity to iodine or povidone or any other of the excipients listed in this leaflet.
- Not to be used in hyperfunction of the thyroid (hyperthyroidism), other manifest thyroid diseases esp. nodular colloidal goitre, endemic goitre, Hashimoto's thyroiditis, as well as before and after radioiodine therapy for hyperthyroidism, until a lasting cure has been obtained.
- It should not be used for 4 weeks prior to radioiodine scintigraphy or radioiodine treatment or thyroid carcinoma.
- Patients with goitre, thyroid nodules, or other thyroid diseases (especially elderly patients) are at risk of developing thyroid hyperfunction (hyperthyroidism) from the administration of large amounts of iodine.
- Use on babies of very low birth weight (1500 g) is contraindicated.
- Not to be used on patients on concurrent lithium therapy.
- Not recommended for body cavity irrigation.

#### Precautions:

- Povidone-iodine should not cover for a long period large areas of the skin (e.g., not to more than 10% of the total body surface and for not longer than 14 days) unless strictly indicated. Even after the end of the treatment (up to 3 months) one should look for the early symptoms of possible hyperthyroidism and if necessary the thyroid function should be monitored.
- Special caution is needed when regular applications to broken skin are made to patients with pre-existing renal insufficiency.
- Avoid solutions containing a detergent if treating open wounds with povidone-iodine.
- For external use only. In pre-operative preparation, avoid "pooling" beneath the patient. Prolonged exposure to wet solution may cause

allergy or contact dermatitis or rarely, severe skin reactions. Skin burns due to "pooling" may occur.

- In instances of local irritation or sensitivity, discontinue use. Do not heat prior to application.
- Keep out of the reach of children

#### **Interactions with other drugs and other forms of interactions:**

- 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 products containing enzymatic component, hydrogen peroxide, silver and taurolidine lead to a weakening effect of both substances.
- Simultaneous use with mercury products may lead to the formation of a substance, which can damage the skin.
- Absorption of iodine from povidone-iodine through either intact or damaged skin may interfere with tests or thyroid function and can make a planned treatment of the thyroid with iodine impossible. After the end of the treatment an interval of at least 1-2 weeks should be allowed before a new scintigram is carried out.
- Contamination with Povidone-Iodine of several types of tests for the detection of occult blood in faeces or blood in urine may produce false-positive results.

#### **Pregnancy and breast-feeding:**

**During pregnancy and lactation, BETADINE® Antiseptic Solution should only be used if strictly prescribed by the doctor and its use should be kept to the absolute minimum,** as absorbed iodine can cross the placental barrier and can be secreted in breast milk. This also applies to newborns and infants up to age of 2 years. Povidone-iodine use may induce transient hypothyroidism in the foetus or in the newborn. Povidone-iodine should be avoided in such situations. In these cases a check of the child's thyroid function is necessary, especially in areas known for endemic low dietary iodine and tendency to goitre.

Also, any possible ingestion of the solution by the infant must be absolutely avoided.

#### **4- How to use BETADINE® Antiseptic Solution?**

Route of administration: Topical.

Adults, the elderly and children: Apply full strength as a preoperative antiseptic skin cleanser. Avoid pooling both under the patient and in the skin folds. Wash off excess solution before using occlusive dressings. Povidone iodine is not recommended for regular use in neonates and is contraindicated in very low birth weight infant (below 1500 grams).

Spread the solution, undiluted, onto the parts to be treated.

After drying, an air-permeable film is formed, which can be easily washed off with water. The solution can be applied several times a day.

**For disinfection of the hands the procedure is as follows:**

##### **1) Hygienic disinfection of the hands:**

3 ml undiluted - allow to work in for one minute.

##### **2) Surgical disinfection:**

2x5 ml undiluted - allow to work in 5 minutes.

**For disinfection of the skin the procedure is as follows:**

##### **1) Application on skin with few sebaceous glands**

Before injections, punctures and surgical operations, allow the solution to act for at least 1 minute.

##### **2) Application on skin with many sebaceous glands**

Before all operations allow the solution to act for at least 10 minutes, keeping the skin constantly moist.

In the disinfection of the skin before operations, avoid the formation of pools of the solution under the patient's body (because of possible irritation of the skin).

BETADINE® Antiseptic Solution can be used diluted for rinsing and washing. For different uses dilutions are recommended. You may ask your doctor or your pharmacist about these. If there is no improvement of the symptoms after several days (2-5 days) regular application, you should consult your doctor.

#### **Overdose**

In the event of accidental or deliberate ingestion of BETADINE® Antiseptic Solution, contact immediately your doctor or your nearest hospital.

Symptoms: Metallic taste in mouth, increased sali-

vation burning or pain in the throat or mouth, irritation and swelling of the eyes, breathing difficulties due to pulmonary oedema, skin reactions gastrointestinal upset and diarrhoea, metabolic acidosis, hypernatraemia and renal impairment.

Therapy: Symptomatic and supportive treatment should be provided, with special attention to electrolyte balance and renal and thyroid function.

### 5- Side effects

Rarely, hypersensitive skin reactions may occur (e.g. delayed contact-allergic reactions, which can appear in the form of itching, redness, small blisters or similar manifestations). Involvement of other organs has been reported in isolated cases.

In single cases acute, generalized, allergic reactions with drop in blood pressure and/or shortness of breath (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 racing pulse or a feeling of unrest (see under Special Warnings and Precautions).

Following uptake of large amounts of Povidone-Iodine (e.g., in the treatment of burns), the appearance of additional disorders of electrolyte and serum osmolarity, impairment of renal function with acute renal failure and metabolic acidosis have been described.

If you experience any of the above side effects or any other unusual effects, stop using the product and consult your doctor.

### 6- Storage Precautions:

- Store at or below 25°C.
- Do not use after the expiry date (see date printed on the packing)
- Keep out of the reach of children.

### 7- Further information:

Manufacturer & Marketing Authorization Holder:  
MUNDIPHARMA PHARMACEUTICALS LTD, 13

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