BETADINE® ANTISEPTIC SOLUTION

Active substnace: polyvidone-iodine (PVP-iodine)
Broad spectrum microbicide
For use on the skin, mucus membraneous and wounds.

Composition

100 ml Betadine antiseptic solution contains: 10 g polyvidone-iodine (poly(1-vinyl-2-pyrrolidone) iodine complex), mean molecular weight of PVP: 40000, with a content of 11% available iodine. Inactive ingredients: Glycerol, nonoxinol 9, potassium iodate, sodium monohydrogen phosphate.

Indication

For single application: Disinfection of the intact skin or antiseptic treatment of the mucous membranes, for example before operations, biopsies, injections, punctures and blood sampling.

For repeated, short-term application: Antiseptic treatment of wounds, burns, infected and superinfected dermatoses. For hygienic and surgical disinfection of the hands.

Contraindications

Not to be used in hyperfunction of the thyroid (hyperthyroidism), other manifest thyroid disease, the very rare chronic skin inflammation dermatitis herpetiformis Duhring, in known hypersensitivity to iodine as well as before and after radiotherapy of the thyroid gland with iodine (radioiodine therapy), until a lasting cure has been obtained.

Patients with goiter or following thyroid diseases and also patients with a particular predisposition for disturbances of the thyroid function (especially elderly patients) are at risk of developing thyroid hyperfunction (hyperthyroidism). Betadine antiseptic solution should therefore not be applied over a long period and to large area 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.

In patients undergoing concomitant lithium therapy, regular use of Betadine antispetic solution is to be avoided.

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. This also applies to newborns and infants up to age of 6 months. Povidone-iodine use may induce transient hypothyroidism in the fetus or in the newborn. In these cases a check of the child’s thyroid function is necessary. Also, any possible ingestion of the solution by the infant must be absolutely avoided.
Note:
Due to the oxidative effect of Betadine antiseptic solution various diagnostic agents can show false-positive results (e.g. tests with toluidine or gum guaiac for the determination of hemoglobin or glucose in the stool or the urine).

During the use of Betadine antiseptic 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], radiiodine diagnostics) and can make a planned treatment of the thyroid with iodine (radiiodine therapy) 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.

Side effects
Very 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.

The long-term use of Betadine Antiseptic 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 Contraindications). If you experience any of these symptoms, you should immediately consult your doctor.

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.

Interactions with other drugs
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 a so-called enzymatic component leads to a weakening of the effects of both substances. The same thing can happen if disinfectants containing silver, hydrogen peroxide or taurolidine are concomitantly used.

The use of mercury-containing wound-treatment products at the same time or shortly after Betadine Antispeci Solution can, under certain circumstances, lead to the formation of a substance (from iodine and mercury) which can damage the skin.

Dosage instructions and mode and duration of application
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 for one minute.
2) Surgical disinfection: 2 x 5 ml undiluted - allow to work in for 5 minutes.

For disinfection of the skin the procedure is as follows:

Application on skin with few sebaceous glands
Before injections, punctures and surgical operations, allow the solution to act for at least 1 minute.

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 operation, 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 undiluted or diluted for rinsing and washing. For different uses different 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 applications, you should consult your doctor.

**Storage Precautions**
Store at or below 25°C.
Note:
Do not use after the expiry date (see printed on the packaging)
Keep medicine out of the reach of children.

**Pharmaceutical forms and packing sizes**
30 ml solution, 120 ml solution, 500 ml, hospital packs.

**Manufacturer**
Mundipharma GmbH.
Mundipharma Str. 2, D-65549 Limburg / Lahn, Germany

**Distributor**
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