BETADINE OINTMENT

(non-greasy, washable)

Active substance: polyvidone-iodine (PVP-iodine)

Broad-spectrum microbicide

For use on the skin and on wounds

Compositon

1 g Betadine ointment contains: 100 mg polyvidone-iodine (poly(1-vinyl-2-pyrroliodone) iodine complex, mean molecular weight of PVP: 40000, with a content of 10% available iodine. Inactive ingredients: macrogols 400, 1000, 1500 and 4000.

Indications

For repeated application as an antiseptic, for a limited time, on damaged skin, such as decubitus ulcer (bedsore), ulcus cruris (leg ulcer), superficial wounds and burns, infected and superinfected dermatoses.

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, povidone or polyethylene glycol 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 alsp patients with a particular predisposition for disturbances of the thyroid function (especially elderly patients) are at risk of developing thyroid hyperfunction (hyperthyroidism). Betadine ointment should therefore not be applied over a long period and to 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.

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

During pregnancy and lactation, Betadine onitment 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. 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 ointment 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 ointment 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 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 ointment 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 doctors.

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 you use 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 ointment 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 ointment evenly over the area of damaged skin, once to several times a day. If necessary, a dressing can be applied. If there is no improvement of the symptoms after several days (2-5 days) regular application of the ointment, you should consult your doctor.
Storage Precautions
Store at or below 25°C.

Note:
Do not use after the expiry date (see date printed on the packing).

Keep medicines out of the reach of children.

Nature And Contents Of Container
Tubes with 10 g and 20 g ointment. Jars with 250 g ointment.

Manufacturer
Mundipharma GmbH.
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Distributor
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