Read this leaflet carefully. It provides a summary of information about your medicine. If you have further questions, please ask your doctor or your pharmacist

Directions for Use

Braunol

Active substance: povidone iodine

Composition
100 g solution contains:

Active substance:
7.5 g povidone iodine with a content of 10 % available iodine

Other ingredients:
Sodium dihydrogen phosphate dihydrate, sodium iodate, macrogol lauryl ether 9 EO, sodium hydroxide, purified water

Pharmaceutical form
Cutaneous solution

Pharmaco-therapeutic group
Antiseptic and disinfectant containing povidone iodine for application to skin, mucosa and wounds

Indications
Braunol is used for the prevention and treatment of infections of the intact or broken skin and mucous membranes in adults, children and term newborn infants.

For single application:
Disinfection of intact external skin and mucous membrane antisepsis , e.g. before surgery , biopsies, injections, punctures, blood sampling and catheterisations.

For repeated application, limited in time:
Antiseptic treatment of wounds (e.g. pressure sores, leg ulcers), burns, infected dermatoses.
Hygienic and surgical hand disinfection.

Contraindications
Do not use Braunol:
- if you are allergic to iodine or any of the other ingredients
- in case of thyroid diseases
- in case of dermatitis herpetiformis syndrome (rare skin disease with burning, itching and different symptoms of the skin above all on arms, legs, shoulders and buttocks)
- before and after radio-iodine-therapy
- in case of very low birth weight infants (birth weight <1,500 g)

Warnings and precautions
- When used to disinfect the skin pre-operatively, care should be taken to prevent the preparation from "pooling" under the patient, as this may cause skin irritation.
- Prior to application the history of allergy should be sought. Povidone iodine might cause anaphylactic reactions in susceptible persons.
- in patients with goitre or after thyroid disease Braunol should not be applied for long periods and to large areas (for example, to more than 10 % of the total body area and for more than 14 days). In such cases, up to 3 months after the withdrawal of the treatment, these patients should be carefully tested for early symptoms of hyperthyroidism, and if necessary, functional thyroid surveillance should be carried out.
- in patients concomitantly undergoing lithium therapy, regular use of Braunol should be avoided.
- Avoid regular application in patients with renal impairment.

Interference with diagnostic tests
Due to the oxidizing effect of povidone iodine in certain diagnostic analysis, falsely-positive counts can result (e.g. o-toluidine or guaiac resin for determination of haemoglobin or glucose in stool or urine).

Povidone iodine can reduce the iodine uptake of the thyroid gland. This can disrupt tests on the thyroid gland (scintiscanning, determination of protein bound iodine, radio-iodine-diagnostic) and can thus make radio-iodine-therapy impossible. A new scintigram should not be performed within 1 - 2 weeks after treatment with povidone iodine.

Pregnancy and lactation
During pregnancy and lactation, Braunol should be used only on the doctor's advice and its use should be extremely restricted. After the application of Braunol, functional thyroid testing of the child is recommended.

Care should be taken to prevent the accidental oral intake of Braunol by babies via contact with treated parts of the mother's body during lactation.

Children
Avoid regular use in newborn infants. After Braunol has been used, functional thyroid tests should be carried out.

Care should be taken to prevent any accidental oral intake of the preparation by infants.

Older patients
In older patients the risk of subsequent iodine-induced hyperthyroidism is increased and these patients should seek the doctor's advice before use of Braunol. In older patients with goitre and in predisposed patients with functional thyroid disorder Braunol should be applied for long periods and to large areas only on the doctor's advice. If necessary, functional thyroid surveillance should be carried out.

What have you to note further?
Stains on clothes can be removed with soap and water. Stubborn stains can be easily removed with liquid ammonia or thiosulfate solution.

Interactions
Other medicines and Braunol
When povidone iodine is used concomitantly with enzymatic wound treatments, disinfectants containing silver, hydrogen peroxide, or taurolidine, mutual weakening of efficacy may occur.

Braunol may not be used concomitantly or shortly after application of disinfectants containing mercury, since possibly an agent is formed that causes acid burns.

In patients concomitantly undergoing lithium therapy, regular use of Braunol should be avoided, especially if the surface treated is large. Absorbed iodine can support hypothyroidism possibly caused by lithium.

Other interactions
Povidone iodine reacts with proteins and certain other organic compounds, e.g. blood or pus components, whereby its effectiveness may be reduced.

Dosage and method of administration
Skin disinfection and mucous membrane antisepsis
Apply undiluted Braunol to the area to be treated until it is completely wet. It is necessary to keep the skin moistened:
On skin with few sebaceous glands:
- in case of injections and punctures at least 15 seconds
- before applications such as punctures of joints or of the cerebrospinal channel the minimum application period is 1 minute (repeated application, if necessary).

On sebaceous skin areas (e.g. head, the upper chest, and the area between the shoulder blades)
in each case at least 10 minutes (repeated application).

Attention**:** When used to disinfect the skin pre-operatively, take care to prevent the preparation from "pooling" under the patient, as this may cause skin irritation.

Wound treatment
For the antiseptic treatment of superficial wounds and burns, apply Braunol undiluted.

Hand disinfection
Apply Braunol undiluted:
- Hygienic hand disinfection: Rub 3 ml Braunol into the hands. After the preparatory period of 1 minute, wash the hands.
- Surgical hand disinfection: Rub 2 x 5 ml Braunol into the hands for a period of 5 minutes. Keep the hands moistened with the undiluted preparation during the whole preparatory period.

Rinsing and washing
Braunol can be used diluted for antiseptic rinsing, washing and bathing purposes. The following dilutions are given as guidelines:
- Irrigation performed as part of the treatment of wounds (e.g. decubitus, ulcus cruris and gangrene) and the peri-operative prevention of infection 1:2 to 1:20
- Antiseptic washes 1:2 to 1:25, antiseptic single-limb baths approximately 1:25, antiseptic body-baths approximately 1:100

The preparation can be diluted with normal tap water. Whenever isotonic conditions are required, a physiological salt solution or Ringer

solution can be used. All dilutions have to be freshly prepared and used immediately.

Notes:
For total antiseptic bathing of the patient, first fill the bath with water, then add the required quantity of Braunol. This prevents the release of iodine containing vapours which may cause a yellowing of the surrounding material.

The brown colour of Braunol is a characteristic of the preparation which signals its efficacy. A conspicuous loss of colour shows that the preparation has lost its efficacy.

Frequency and duration of the application
When Braunol is applied repeatedly, the frequency and duration of the applications will depend on the case in hand.

Braunol can be applied once or several times a day.

Treatment of wounds should be continued until there are no signs of infection or until there is no obvious risk of the margins of the wound becoming infected. If the condition has not improved after several days of regular treatment (2 to 5 days) or if a relapse of the infection should occur after Braunol treatment has been stopped, please tell your doctor.

Possible side effects

Relevant side effects or signs you should pay attention to, and measures to take if you are affected
Very rarely (may affect up to 1 in 10,000 people) may occur:
- Cutaneous reactions due to hypersensitivity (allergy), e.g. contact allergy reactions of the late type in the form of itching, redness, blisters etc.
- Acute reactions of the immune system (anaphylactic reactions) with the involvement of other organs (e.g. skin, respiratory tract, circulatory system).

Discontinue the use of Braunol and immediately consult your doctor, if you are affected by any of these side effects.

Other side effects
- Uncommon (may affect up to 1 in 100 people): At the beginning of the treatment a temporary local burning sensation may occur.
- A significant level of iodine intake can result from the long-term application of Braunol to extensive wounds and burns. Very rarely, in predisposed patients iodine-induced hyperthyroidism can occur, partly with symptoms like increased pulse rate or restlessness (see section 2).
- Following resorption of large quantities of povidone iodine (e.g. in treatment of burns) disturbance in electrolyte- and serum osmolarity, renal failure and metabolic acidosis have been described.

Storing Braunol

Keep out of reach and sight of children.

Do not store above 30°C

Do not use after the expiry date on the label.

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