Directions for Use
Braunoderm

50 g Isopropyl Alcohol + 1 g Povidone Iodine Cutaneous Solution

Composition

100 g of solution contain

Active substances:

Isopropyl Alcohol	50 g
Povidone Iodine	1 g (equivalent to 100 mg Iodine)

Excipients:

Potassium Iodide, Sodium Dihydrogen Phosphate Dihydrate and Purified Water

Pharmaceutical Form

Cutaneous solution

Braunoderm is a clear, brown solution for application on the skin (cutaneous solution).

It is available in bottles of 250 ml and 1000 ml and in containers of 5L.

Pharmaco-Therapeutic Group

Antiseptics and Disinfectants

Braunoderm is an alcoholic skin disinfectant.

The active ingredients, isopropyl alcohol and povidone iodine, are antiseptic agents with a wide range of activity. Braunoderm is effective against bacteria [incl. strains which are resistant against antibiotics, e.g. MRSA (Methicillin Resistant Staphylococcus aureus)], mycobacteria (incl. Mycobacterium tuberculosis), fungi and many viruses (e.g. Poliovirus, Vaccinia virus).

Indications

Braunoderm is intended for disinfection of intact skin, e.g. before.

- operations
- injections
- punctures
- catheterisations
- taking of blood samples
- vaccinations

Contraindications

Do not use Braunoderm:

- in case of thyroid diseases
- in case of dermatitis herpetiformis syndrome (a 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
- if the patient is allergic to isopropyl alcohol or iodine or any of the other ingredients of Braunoderm listed above

Special Warnings and Precautions for Use

Take special care with Braunoderm:

In newborn infants and babies Braunoderm should be used under medical observation only due to the risk of resorption of isopropyl alcohol or iodine through the skin and the risk of irritation of the neonate's skin.

It is mandatory that the solution is allowed to dry from the skin after application. Occlusive conditions may result in severe skin burns. If used to disinfect the skin pre-operatively, care must be taken to prevent the preparation from "pooling" under the patient.

Before use of electrical equipment allow Braunoderm to dry on skin!

Braunoderm is flammable (Flash point 21 to 22 °C). That means that at temperatures above 21 to 22 °C, Braunoderm may be ignited by sparks, burning cigarettes, open flames and other sources of ignition.

Do not swallow. Do not apply on injured skin, eyes or mucous membranes.

Braunoderm is for external use only. If somebody swallows Braunoderm inadvertently, he may suffer from symptoms similar to acute alcohol poisoning. Immediate emergency medical care is needed because large doses could stop breathing or impair conscious-ness with a danger of inhaling vomit. Initiate vomiting under medical advise only.

In case of accidental eye contact, the open eye and the inner side of the eyelid has to be rinsed with plenty of water immediately for several minutes. If irritation continues please seek immediate medical advice.

Effects on ability to drive and use machines:

Braunoderm does not affect the ability to drive or operate machinery.

Children:

For the treatment of newborns (especially premature babies) and infants up to the age of 6 months the risks of skin irritation, alcohol resorption, and of affecting the infant's thyroid gland by the content of iodine have to be taken into account. Braunoderm should be used in these cases on the doctor's advice only. After application on large areas it is necessary to monitor the thyroid function. Accidental oral uptake of Braunoderm by the infant has to be avoided.

Elderly patients:

The risk of inducing hyperactivity of the thyroid gland by iodine is enhanced in elderly patients. Braunoderm should be used on the doctor's advice only.

Important information about some of the ingredients of Braunoderm:

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

Effects on 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 and 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, Braunoderm, like all preparations containing iodine, should be used only when strictly indicated and its use should be extremely restricted.

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

Interactions

Using other medicines:

When povidone iodine is used concomitantly with disinfectants containing silver, hydrogen peroxide or taurolidine, mutual inactivation may occur.

Because of the danger of severe skin irritation by mercury iodide, povidone iodine may not be used with mercury compounds at the same time or subsequently.

Dosage

The recommended dosage is

Throughout the period of application the skin must remain wetted with the undiluted preparation.

Apply undiluted Braunoderm to the skin area to be disinfected and spread with sterile swab. Wet the skin to be treated completely and then let dry after the exposure time prescribed. Excess solution should be tamponed.

The minimum application period on skin with few sebaceous glands is 15 seconds (injections, punctures). For 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 area above the upper breastbone, and the area between the shoulder blades) the application period is 10 minutes (repeated application).

Undesirable Effects

Like all medicines, Braunoderm can cause side effects, although not everybody gets them.

Cutaneous reactions due to hypersensitivity (allergy) occur very rarely, e.g. contact allergy reactions of the late type can occur in the form of itching, redness, blisters, etc.. In isolated cases, the involvement of other organs has been reported.

Cases of local alcohol-induced irritation symptoms (e.g. itching, redness, especially after frequent application of Braunoderm) are uncommon. Symptoms of dry skin may occur uncommonly in seasons of low air humidity (especially in winter). The application of a skin caring cream is recommended in such cases.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Expiry Date

The product must not be used beyond the expiry date stated on the labelling. After the first opening of the container, Braunoderm will maintain its quality for 12 months, but not beyond the expiry date.

Instructions for Storage/Use/Handling

Keep out of the reach and sight of children.

Keep container tightly closed.

Do not store above 30 °C

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to maintain the environment.

ID **Reg. No.:** KEMENKES RI PKL 20502700238

Indikasi

Desinfeksi untuk kulit sebelum operasi, suntikan, tusukan, kateterisasi, mengambil sampel darah, vaksinasi.

Dosis

Dosis yang direkomendasikan adalah

Selama periode aplikasi kulit harus tetap dibasahi dengan persiapan murni.

Terapkan Braunoderm murni ke area kulit yang akan didesinfeksi dan menyebar dengan swab steril. basahi kulit untuk diobati sepenuhnya dan kemudian biarkan kering setelah waktu pemaparan yang ditentukan. kelebihan solusi harus disimpan.

MY **Reg. No.:** MAL 19963148X

Date of last revision: 08/2010

ID Imported by:
PT. B. Braun Medical
Indonesia
Jakarta – Indonesia

MY Licence Holder in Malaysia
B. Braun Medical Industries S/B
11900 Bayan Lepas, Penang
Malaysia

Manufactured by:
B. Braun Medical AG
Seesatz 17
6204 Sempach
Switzerland

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Released by:
B. Braun Melsungen AG
34209 Melsungen
Germany

87276 - 2015-05-04