

SCHEDULING STATUS: S0

PROPRIETARY NAME (AND DOSAGE FORM):

BETADINE® FIRST AID CREAM (CREAM)

COMPOSITION:

Each 1 g contains povidone- iodine 50 mg, equivalent to 5 mg available iodine in a water soluble base.

PHARMACOLOGICAL CLASSIFICATION:

A 13.1 Antiseptics, disinfectants and cleansing agents.

PHARMACOLOGICAL ACTION:

Povidone-iodine is a multivalent broad spectrum local antiseptic having bactericidal and fungicidal properties. The effect on vegetative cells of various bacteria and fungi is due to the liberation of free iodine from the complex. *In vitro* studies have also shown some antiviral activity.

INDICATIONS:

As an antiseptic in minor:

- Skin infections
- Wounds, cuts and abrasions
- Burns

CONTRA-INDICATIONS:

Sensitivity to povidone-iodine. Patients with non-toxic nodular colloid goitre should not use povidone-iodine. Application to large areas of broken skin should be avoided as excessive absorption of iodine may occur.

WARNINGS:

1. Not to be used by persons who are allergic to iodine.
2. Not to be used in pregnancy or by lactating women.

DOSAGE AND DIRECTIONS FOR USE:

The affected area should be cleaned and dried. Apply **BETADINE® FIRST AID CREAM** liberally and cover with a dressing or bandage. **BETADINE® FIRST AID CREAM** may be used as often as required.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Hypersensitivity and local irritation may occur. However, if irritation, swelling or redness occur, discontinue treatment and consult your physician. Hypothyroidism may occur after topical application to neonates. Absorption of povidone-iodine may interfere with thyroid function tests.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT:

Systemic effects include metabolic acidosis, hypernatraemia and renal impairment. These effects could occur if applied to large areas or denuded skin. Treatment is symptomatic and supportive.

IDENTIFICATION:

BETADINE® FIRST AID CREAM

is a homogeneous reddish-brown viscous cream, free from lumps.

PRESENTATION:

An aluminium tube with a polypropylene cap containing 15 g or 40 g of cream.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

27/13.1/0062

Export Details:

Namibia: NS0

Registration No. 05/13.1/0176

Botswana: S3

Reference No. B9300320

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

24 November 1992

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SKEDULERINGSTATUS: S0

EIENDOMSNAAM (EN DOSEERVORM):

BETADINE® FIRST AID CREAM (ROOM)

SAMESTELLING:

Elke 1 g bevat povidoonjodium
50 mg, gelyk aan 5 mg beskikbare jodium in 'n wateroplosbare basis.

FARMAKOLOGIESE KLASSIFIKASIE:

A 13.1 Antiseptika, ontsmettingsmiddels en reinigingsmiddels.

FARMAKOLOGIESE WERKING:

Povidoonjodium is 'n multivalente breëspektrum plaaslike antiseptiese middel wat kiemdodende en swamdodende eienskappe besit. Die uitwerking op groeiende selle van verskeie bakterieë en swamme is te wyte aan die vrystelling van vry jodium vanuit die samestelling. *In vitro* studies het ook soms antivirale aktiwiteit getoon.

INDIKASIES:

As 'n antiseptiese middel by geringe:

- Velinfeksies
- Wonde, snye en skaafplekke
- Brandwonde

KONTRA-INDIKASIES:

Gevoeligheid vir povidoonjodium. Pasiënte met 'n nie-toksiese nodulêre kolloïedkropgeswel behoort nie povidoonjodium te gebruik nie. Aanwending aan groot oppervlakte stukke vel moet vermy word omdat oormatige absorpsie van jodium kan plaasvind.

WAARSKUWINGS:

1. Moet nie gebruik word deur pasiënte wat allergies is vir jodium nie.
2. Moet nie gebruik word gedurende swangerskap of deur borsvoedende vroue nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Die aangetaste deel moet skoon en droog gemaak word.

BETADINE® FIRST AID CREAM word dan mildelik aangewend en 'n wonddekking of verband opgesit. **BETADINE® FIRST AID CREAM** kan so dikwels as nodig gebruik word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Hipersensitiwiteit en plaaslike irritasie kan voorkom. As 'n irritasie, swelling of rootheid egter opgemerk word, moet die behandeling gestaak en 'n geneesheer geraadpleeg word. Hipotireose kan voorkom na plaaslike aanwending aan pasgebore babas. Povidoonjodiumabsorpsie kan met die skildklierfunksie-toetse inmeng.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Sistemiese gevolge sluit metabolisme asidose, hipernatremie en nierversaking in en kan voorkom as dit aan groot dele of aan geskaafde vel aangewend word. Behandeling is simptome en ondersteunend.

IDENTIFIKASIE:

BETADINE® FIRST AID CREAM is 'n homogene rooibruin viskeuse room, sonder enige klonte.

AANBIEDING:

'n Aluminium buis met 'n polipropileen dop wat 15 g of 40 g room bevat.

BERGINGSAAWYSINGS:

Bêre by of benede 25 °C.
HOU BUITE BEREIK VAN
KINDERS.

REGISTRASIENOMMER:

27/13.1/0062

Uitvoer besonderhede:

Namibië: NS0

Registrasienuommer. 05/13.1/0176

Botswana: S3

Verwysingsnommer. B9300320

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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:

24 November 1992

BETADINE® is 'n geregistreerde handelsmerk.