

SCHEDULING STATUS: S0

PROPRIETARY NAME (AND DOSAGE FORM):

BETADINE® ANTISEPTIC OINTMENT

COMPOSITION:

Each 1 g contains povidone- iodine 100 mg, equivalent to 10 mg available iodine.

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. Many viruses, protozoa, yeasts, cysts and spores are also susceptible.

INDICATIONS:

As an antiseptic in:

- Skin infections
- Decubitus ulcers
- Wounds, cuts and abrasions
- Burns
- Postoperative wounds

CONTRA-INDICATIONS:

Sensitivity to povidone-iodine. Povidone-iodine should not be used on patients with non-toxic nodular colloid goitre. 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® ANTISEPTIC OINTMENT** liberally and cover with a dressing or bandage. **BETADINE® ANTISEPTIC OINTMENT** 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 ITS 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® ANTISEPTIC OINTMENT is a smooth, uniform dark brown ointment.

PRESENTATION:

Aluminium cylindrical tube with a polypropylene cap containing 20 g or 100 g of ointment. The tubes are enclosed in printed cartons.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. For external use only.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

G1574 (Act 101/1965)

Export Details:

Namibia: NS0

Registration No. 14/13.1/0383

Botswana: S4

Reference No. B9300325

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

23 January 1987

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SKEDULERINGSSTATUS: S0

EIEDOMSNAAM (EN DOSEERVORM):

BETADINE® ANTISEPTIC OINTMENT (SALF)

SAMESTELLING:

Elke 1 g bevat povidoonjodium 100 mg, gelyk aan 10 mg beskikbare jodium.

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. Baie virusse, protosoë, gisse, siste en spore is ook vatbaar.

INDIKASIES:

As 'n antiseptiese middel by:

- Velinfeksies
- Druksere
- Wonde, snye en skaafplekke
- Brandwonde
- Postoperatiewe wonde

KONTRA-INDIKASIES:

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

WAARSKUWINGS:

1. Moet nie gebruik word deur mense wat allergies is vir jodium nie.
2. Moet nie deur verwagte of borsvoedende vroue gebruik word nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Die aangetaste deel moet skoon en droog gemaak word. **BETADINE® ANTISEPTIC OINTMENT** word dan mildelike aangewend en 'n wonddekking of verband opgesit. **BETADINE® ANTISEPTIC OINTMENT** kan so dikwels as nodig gebruik word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

Hipersensitiwiteit en plaaslike irritasie kan voorkom. As irritasie, swelsel of rooiheid egter opgemerk word, moet die behandeling gestaak, en 'n geneesheer geraadpleeg word. Hipotireose kan voorkom na plaaslike aanwending aan pasgebore babas.

Povidoonjodium absorpsie kan met skildklierfunksie-toetse inmeng.

BEKENDE SIMPTOME VAN OOROOSERING EN BESONERHEDE VAN DIE BEHANDELING DAARVAN:

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

IDENTIFIKASIE:

BETADINE® ANTISEPTIC OINTMENT is 'n gladde, uniform donkerbruin salf.

AANBIEDING

'n Aluminium silindriese buis met 'n polipropileen dop wat 20 g of 100 g salf bevat. Die buise word in gedrukte kartonne verpak.

BERGINGSANWYSINGS:

Bêre by of benede 25 °C. Slegs vir uitwendige gebruik. HOU BUITE BEREIK VAN KINDERS.

VERWYSINGSNOMMER:

G1574 (Wet 101/1965)

Uitvoer besonderhede:

Namibië: NS0

Registrasienuommer. 14/13.1/0383

Botswana: S4

Verwysingsnummer. B9300325

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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:

23 Januarie 1987

BETADINE® is 'n geregistreerde handelsmerk.