

**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)

**NAME AND BUSINESS  
ADDRESS OF THE APPLICANT:**

Mundipharma (Pty) Ltd.,  
Block D, Grosvenor Square,  
Park Lane, Century City,  
Cape Town, 7441,  
South Africa  
www.mundipharma.co.za

**Export Details:**

Namibia: NS0  
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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  
BESONOERHEDE VAN DIE  
BEHANDELING DAARVAN:**

Sistemiese gevolge sluit  
metabooliese 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.

**VERWYSINGSNUMMER:**

G1574 (Wet 101/1965)

**NAAM EN BESIGHEIDSADRES  
VAN DIE APPLIKANT**

Mundipharma (Edms) Bpk,  
Blok D, Grosvenor Square,  
Park Lane, Century City,  
Kaapstad, 7441,  
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**Uitvoer besonderhede:**

Namibië: **NS0**  
Registrasienuommer. 14/13.1/0383  
Botswana: **S4**  
Verwysingsnommer. B9300325

**DATUM VAN PUBLIKASIE VAN  
HIERDIE VOUBILJET:**

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