**SCHEDULING STATUS:** S0

**PROPRIETARY NAME AND DOSAGE FORM:**

**BETADINE® SURGICAL SCRUB**

**COMPOSITION:**

Each 100 ml contains 7,5 g povidone-iodine (7,5 % *m/v*) equivalent to 0,75 g 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:**

Disinfection of the hands prior to surgical procedures or in the operating theatre. Preparing the patient's skin prior to surgical procedures or operations. As an antiseptic soap in infected skin conditions. As a general germicidal skin cleanser in consulting rooms.

**CONTRAINDICATIONS:**

Sensitivity to povidone-iodine. Patients with non-toxic nodular colloid goiter should not use povidone-iodine.

**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:**

**Pre-operative washing by operation personnel:**

Wet hands with water. Pour sufficient **BETADINE® SURGICAL SCRUB** onto the palm and spread over both hands. Rub the scrub thoroughly over all areas for two minutes. Use a nail brush, if desired. Add a little water to develop a copious lather. Rinse thoroughly under running water.

**Pre-operative use on patients:**

After the area is shaved, wet it with water. Apply **BETADINE® SURGICAL SCRUB** (1 ml is sufficient to cover about 50 to 75 square cm) and rub in thoroughly for at least two minutes. Use sterile gauze soaked with water to develop a copious lather. Rinse off and dry with dry sterile gauze.

**Consulting room use:**

Use for washing whenever a germicidal soap is required.

For the maximum effect on the hands or patient's skin, proceed as in the above two paragraphs. **NOT FOR DOUCHING PURPOSES.**

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

Hypersensitivity and local irritation may occur. 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:**

Ingestion is unlikely but if accidentally ingested, systemic effects could include metabolic acidosis, hypernatraemia and renal impairment. These effects could occur if the surgical scrub were applied to large areas or to denuded skin. The patient should be taken to a doctor or to the nearest hospital without delay. Treatment is symptomatic and supportive.

**IDENTIFICATION:**

**BETADINE® SURGICAL SCRUB** is an amber-coloured, foaming liquid with a characteristic iodine smell.

**PRESENTATION:**

White or beige, round, high density polyethylene (HDPE) bottle, containing 250 ml liquid with a low density polyethylene (LDPE) transparent spout and a red polypropylene (PP) cap.

**STORAGE INSTRUCTIONS:**

Store at or below 25 ºC.

For external use only.

KEEP OUT OF REACH OF CHILDREN.

**REFERENCE NUMBER:**

G1571 (Act 101/1965)

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

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

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**BETADINE®** is a registered trademark

**SKEDULERINGSTATUS :** S0

**EIENDOMSNAAM (EN DOSEERVORM):**

**BETADINE® SURGICAL SCRUB (CHIRURGIESE WASMIDDEL)**

**SAMESTELLING:**

Elke 100 ml bevat 7,5 g povidoonjodium, (7,5 % *m/v*) gelyk aan 0,75 g 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, giste, siste en spore is ook vatbaar.

**INDIKASIES:**

Ontsmetting van die hande voor spreekkamerprosedures of in die operasiesaal. Voorbereiding van die pasiënt se vel voor spreekkamerprosedures of operasies. ‘n Antiseptiese seep vir besmette veltoestande. As ‘n algemene kiemdodende velreiniger in spreekkamers.

**KONTRA-INDIKASIES:**

Sensitiwiteit vir povidoonjodium. Pasiënte met ‘n atoksiese nodulêre kolloïedkropgeswel behoort nie povidoonjodium te gebruik nie.

**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:**

**Pre-operatiewe reiniging deur die operasiepersoneel:**

Maak die hande nat met water. Gooi voldoende **BETADINE® SURGICAL SCRUB** in die palm en versprei dit oor albei hande. Vryf die skropmiddel twee minute lank deeglik in elke deel in. Gebruik ‘n naelborsel indien nodig. Voeg ‘n bietjie water by om sodoende ‘n weelderige skuim te verkry. Spoel deeglik af onder lopende water.

**Pre-operatiewe gebruik op pasiënte:**

Benat die betrokke deel, nadat dit geskeer is, met water. Wend die **BETADINE® SURGICAL SCRUB** aan (1 ml is genoeg om ongeveer 50 tot 75 vierkante cm te bedek) en vryf dit vir minstens twee minute lank deeglik in. Gebruik steriele gaas wat in water geweek is om ‘n weelderige skuim te verkry. Spoel en droog af met droë steriele gaas.

**Spreekkamergebruik:**

Gebruik vir wasdoeleindes wanneer ‘n kiemdodende seep nodig is. Die maksimum uitwerking word op die hande of die vel van die pasiënt verkry indien daar volgens die aanwysings in die twee paragrawe hierbo, te werk gegaan word. **NIE VIR DOUCHING BEDOEL NIE.**

**NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:**

Hipersensitiwiteit en plaaslike irritasie kan voorkom. Indien irritasie, swelsel of rooiheid egter opgemerk word, moet die behandeling gestaak en ‘n geneesheer geraadpleeg word. Hipotireose kan

voorkom na plaaslike toediening aan pasgebore babas. Povidoonjodiumabsorpsie kan met skildklierfunksie-toetse inmeng.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:**

Inname is onwaarskynlik maar indien per ongeluk ingeneem, kan sistemiese gevolge voorkom wat insluit: metaboliese asidose, hipernatremie en nierbeskadiging . Hierdie gevolge kan plaasvind indien die chirurgiese wasmiddel aan groot oppervlaktes of aan geskaafde vel aangewend word. Die pasiënt moet sonder versuim na ‘n geneesheer of na die naaste hospitaal geneem word. Behandeling is simptomaties en ondersteunend.

**IDENTIFIKASIE:**

**BETADINE® SURGICAL SCRUB** is ‘n amberkleurige, skuimende vloeistof met ‘n kenmerkende reuk van jodium.

**AANBIEDING:**

Wit of roomkleurige, ronde, hoë digtheid poliëtileen (HDPE) bottel, wat 250 ml vloeistof bevat, met ‘n lae-digtheid poliëtileen (LDPE) deursigtige spuit en ‘n rooi polipropileen (PP) dop.

**BERGINGSAANWYSINGS:**

Bêre by of benede 25 °C.

Slegs vir uitwendige gebruik.

HOU BUITE BEREIK VAN KINDERS.

**VERWYSINGSNOMMER:**

G 1571 (Wet 101/1965)

**NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:**

Mundipharma (Edms) Bpk., Blok D, Grosvenor Square, Park Lane, Century City, Kaapstad, 7441, Suid Afrika www.mundipharma.co.za

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**BETADINE®** is ‘n geregistreerde handelsmerk.