SCHEDULING STATUS: **S0**

PROPRIETARY NAME (AND DOSAGE FORM):

BETADINE® ANTISEPTIC SOLUTION

COMPOSITION:

Each 1 ml contains 100 mg povidone-iodine, 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:

Disinfection of wounds, lacerations, abrasions and burns. Prophylaxis against infection in hospital and surgery procedures.

Preparation of skin and mucous membranes prior to surgery. Post- operative application to protect against infection. Treatment of infected skin conditions.

CONTRA-INDICATIONS:

Hypersensitivity to povidone-iodine.

Povidone-iodine solutions should not be used on patients with a non-toxic nodular colloid goiter. Application to large areas of broken skin should be avoided as excessive absorption of iodine may occur.

Absorption of povidone-iodine may interfere with thyroid function tests.

WARNINGS:

1. Not to be used by persons who are allergic to iodine.

2. Not be used in pregnancy or by lactating women.

DOSAGE AND DIRECTIONS FOR USE:

Apply full strength, as a paint, or soak or spray as often as needed.

Shake the bottle before use.

NOT FOR DOUCHING PURPOSES

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Local irritation and sensitivity 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:

Systemic effects include metabolic acidosis, hypernatraemia and renal impairment. These effects could occur if the solution is 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® ANTISEPTIC SOLUTION is an amber-coloured aqueous solution with a characteristic iodine smell.

PRESENTATION:

White or cream, round, high density polyethylene (HDPE) bottle, containing 250 ml solution, fitted with a low density polyethylene (LDPE) transparent spout and a yellow polypropylene (PP) cap.

STORAGE DIRECTIONS:

Store at or below 25 ºC.

For external use only.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

G 1570 (Act 101/1965)

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

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SKEDULERINGSTATUS: S0

EIENDOMSNAAM:
(EN DOSEERVORM) BETADINE® ANTISEPTIC SOLUTION (OPLOSSING)

SAMESTELLING:

Elke 1 ml bevat 100 mg povidoonjodium, 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:

Die ontsmetting van wonde, skeurwonde, skaafplekke en brandwonde. Die voorkoming van infeksie tydens hospitaal- en spreekkamerprosedures. Die voorbereiding van die vel en slymvliese voor operasies. Postoperatiewe aanwending as beskerming teen infeksies. Die behandeling van besmette veltoestande.

KONTRA-INDIKASIES:

Sensitiwiteit vir povidoonjodium.

Povidoonjodiumoplossings moet nie op pasiënte gebruik word met ‘n atoksiese nodulêre kolloïedkropgeswel nie.

Aanwending op groot oppervlaktes stukkende vel moet vermy word omdat oormatige absorpsie van jodium kan plaasvind.

Absorpsie van povidoonjodium kan met skildklierfunksie-toetse inmeng.

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:

Kan in volle sterkte so dikwels as wat nodig mag wees, as ‘n verf of benattingsmiddel aangewend word.

Skud die bottel voor gebruik.

NIE VIR DOUCHING BEDOEL NIE.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Plaaslike irritasie en sensitiwiteit kan voorkom. Indien irritasie, swelsel of rooiheid voorkom moet die behandeling gestaak word en ‘n geneesheer geraadpleeg word.

Hipotireose kan voorkom na plaaslike aanwending by pasgeborenes. Absorpsie van povidoonjodium kan met skildklier-funksie-toetse inmeng.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Sistemiese gevolge sluit metaboliese asidose, hipernatremie en nierbeskadiging in. Hierdie gevolge kan plaasvind indien die oplossing op 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® ANTISEPTIC SOLUTION is ‘n amberkleurige, waterige oplossing met ’n kenmerkende reuk van jodium.

AANBIEDING:

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

BERGINGSAANWYSINGS:

Bêre by of benede 25 °C.

Slegs vir uitwendige gebruik.

HOU BUITE BEREIK VAN KINDERS.

VERWYSINGSNOMMER:

G1570 (Wet 101/1965)

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

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