SCHEDULING STATUS: **S0**

PROPRIETARY NAME (AND DOSAGE FORM):

BETADINE® MEDICATED SHAMPOO

COMPOSITION:

Each 100 ml contains povidone-iodine, 4,0 g (4 % *m/v*) equivalent to 0,4 g available iodine, in a shampoo 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. Many viruses, protozoa, yeasts, cysts and spores are also susceptible.

INDICATIONS:

- Seborrhoeic conditions of the scalp associated with excessive dandruff, pruritis, scaling, exudation and erythema.
- Pityriasis capitis.
- Infected lesions of the scalp - pyodermas (furunculosis, infective folliculitis and impetigo).

CONTRA-INDICATIONS:

Sensitivity to iodine. Povidone-iodine should not be used on patients with non-toxic nodular colloid goitre.

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:

After wetting the hair, apply an adequate amount of the shampoo, using warm water to lather. Rinse. Repeat the application and massage into the scalp with the fingertips.

Allow to remain on the scalp for at least five minutes.

Again work up a lather and rinse thoroughly. Repeat the treatment at least twice weekly until improvement is noted.

Afterwards use **BETADINE® MEDICATED SHAMPOO** once a week.

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:

Ingestion is unlikely but if accidentally ingested systemic effects could include metabolic acidosis, hypernatraemia and renal impairment. These effects could occur if the shampoo were applied to large areas or denuded skin.

The patient should be taken to a doctor or the nearest hospital without delay.

Treatment is symptomatic and supportive.

IDENTIFICATION:

BETADINE® MEDICATED SHAMPOO is a dark brown liquid free from suspended material or sedimentation.

PRESENTATION:

White or beige, high density polyethylene (HDPE) bottle containing 125 ml of product, fitted with a low density polyethylene (LDPE) transparent spout and a red polypropylene cap.

STORAGE INSTRUCTIONS:

Store at or below 25 ºC.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

G1572 (Act 101/1965)

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

Mundipharma (Pty) Ltd.,
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BETADINE® is a Registered Trade Mark

SKEDULERINGSTATUS: S0

EIENDOMSNAAM (EN DOSEERVORM): BETADINE® MEDICATED SHAMPOO (MEDISINALE SJAMPOE)

SAMESTELLING:

Elke 100 ml bevat: povidoonjodium 4,0 g (4 % *m/v*) gelyk aan 0,4 g beskikbare jodium, in 'n sjampoebasis.

FARMAKOLOGIESE KLASSIFIKASIE:

A 13.1 Antiseptika, ontsmettings- en reinigingsmiddels

FARMAKOLOGIESE WERKING:

Povidoonjodium is 'n multivalente breëspektrum plaaslike ontsmettingmiddel 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 van die samestelling. Baie virusse, protosoë, giste, siste en spore is ook vatbaar.

INDIKASIES:

- Seboreetoestande van die kopvel, gepaard met oormatige skilfers, jeuk, afskilfering, uitsyfering en eriteem.
- Pitiriasis capitis.
- Besmette letsels aan die kopvel - piodermas (furunkulose, besmetlike follikelontsteking en impetigo).

KONTRA-INDIKASIES:

Sensitiwiteit vir jodium. Pasiënte met 'n nie-toksiese nodulêre kolloïedkropgeswel behoort nie povidoonjodium te gebruik nie.

WAARSKUWINGS:

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

DOSIS EN GEBRUIKSAANWYSINGS:

Maak die hare nat en gebruik sjampoe en warm water om 'n weelderige skuim te kry. Spoel af. Herhaal die aanwending en masseer die sjampoe met die vingerpunte in die kopvel in. Laat dit minstens vyf minute lank op die kopvel bly. Vryf weer totdat dit goed skuim en spoel deeglik af. Herhaal die behandeling minstens twee maal per week totdat 'n verbetering merkbaar is. Gebruik die **BETADINE® MEDICATED SHAMPOO** daarna gereeld een keer per week.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Sensitiwiteit en plaaslike irritasie kan voorkom. Indien irritasie, swelsel of rooiheid voorkom, hou op met die behandling en raadpleeg 'n geneesheer. Hipotireose mag plaasvind na plaaslike aanwending by pasgeborenes. Povidoonjodiumabsorpie kan met die skildklierfunksie-toetse inmeng.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Inname is onwaarskynlik maar indien per ongeluk ingeneem kan sistemiese uitwerking die volgende insluit : metaboliese asidose, hipernatremie en nierbeskadiging. Hierdie uitwerking kan plaasvind indien die sjampoe op groot oppervlaktes of op ontblote vel aangewend word. Die pasiënte moet sonder versuim na 'n geneesheer of die hospitaal geneem word.

Behandling is simptomaties en ondersteunend.

IDENTIFIKASIE:

BETADINE® MEDICATED SHAMPOO is 'n helder donkerbruin vloeistof sonder enige sedimentasie.

AANBIEDING:

Wit of roomkleurige,hoë-digtheid poliëtileen (HDPE) bottel wat 125 ml produk bevat, met 'n lae digtheid poliëtileen (LDPE) deursigtige spuit en 'n rooi polipropileen (PP) prop.

BERGINGSAANWYSINGS:

Bêre by of benede 25 ºC.

HOU BUITE BEREIK VAN KINDERS.

VERWYSINGSNOMMER:

G1572 (Wet 101/1965)

Uitvoer besonderhede:
Namibië: NS0
Registrasienommer. 14/13.1/0385

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DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:

23 Januarie 1987

BETADINE® is ‘n geregistreerde handelsmerk