**SCHEDULING STATUS:** S0

**PROPRIETARY NAME AND DOSAGE FORM**

**BETADINE® MOUTHWASH & GARGLE (SOLUTION)**

**COMPOSITION:**

Each 100 ml contains povidone-iodine 1,0 g (1 % *m/v*) equivalent to 0,1 % *m/v* available iodine.
Contains 7,1 % *v/v* alcohol.
Sugar free.

**PHARMACOLOGICAL CLASSIFICATION:**

A 16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics.

**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:**

**BETADINE® MOUTHWASH & GARGLE** is recommended for relief of painful infections and inflammatory conditions of the mouth and pharynx, and as a routine mouthwash.

**INFECTIONS:** Aphthous ulcers, gingivitis, stomatitis and pharyngitis due to superficial infections. Prophylaxis during and after oral surgery.

**CONTRA-INDICATIONS:**

- Sensitivity to povidone or iodine.
- Patients with hyperfunction of the thyroid (hyperthyroidism), other manifested thyroid diseases (thyroid disorder) and non-toxic nodular colloid goitre.

**WARNINGS:**

1. Do not heat before use.
2. In instances of skin irritation, contact dermatitis or hypersensitivity, discontinue use.

**INTERACTIONS:**

Absorption of iodine from **BETADINE® MOUTHWASH & GARGLE** may interfere with thyroid function tests and can make a planned treatment of the thyroid with iodine (radioidone therapy) impossible. After the end of the treatment an appropriate interval should be allowed before a new scintigram is carried out.

Regular or prolonged use should be avoided in patients receiving concomitant lithium therapy.

**PREGNANCY AND LACTATION:**

During pregnancy and lactation, **BETADINE® MOUTHWASH & GARGLE** should only be used if strictly indicated, and its use should be kept to an absolute minimum.

Absorbed iodine can cross the placental barrier and can be secreted into breast milk. Although no adverse effects have been reported from limited use, caution should be recommended and therapeutic benefit must be balanced against possible effects of the absorption on foetal thyroid function and development.

**DOSAGE AND DIRECTIONS FOR USE:**

**As a mouthwash:** Dilute one part of **BETADINE® MOUTHWASH & GARGLE** with two parts of water, rinse mouth thoroughly and spit out, or use as directed by physician or dentist.

**For infections of mouth and throat:** Use full strength and rinse or gargle for 30 seconds then spit out, repeat hourly, or as directed by physician or dentist.

**For children under 3 years**: Dilute one part **BETADINE® MOUTHWASH & GARGLE** with three parts water and paint the mouth with the aid of a cotton-bud.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

**Side-effects:**

The following side-effects have been reported, but the frequency is unknown.

***Skin and subcutaneous tissue disorders***

Hypersensitivity and local irritation may occur, for example urticaria, pruritus, erythema, small blisters, angioedema, or similar manifestations.

**Special Precautions:**

If irritation, swelling or redness occurs, discontinue treatment and consult your physician.

If severe or persistent sore throat, or sore throat accompanied by high fever, headache, nausea and vomiting occur, consult your physician promptly as these symptoms may indicate a serious condition.

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

Regular or prolonged use should be avoided in patients with thyroid disorders.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

Should ingestion occur, symptoms of acute poisoning are a disagreeable metallic taste, vomiting, abdominal pain and diarrhoea. Anuria may occur 1 to 3 days later; death may be due to circulatory failure, oedema of the glottis resulting in asphyxia, aspiration pneumonia or pulmonary oedema.

Oesophageal stricture may occur if the patient survives the acute stage.

For treatment of acute poisoning, supply patient with draughts of milk and starch mucilage. Lavage may be attempted if there is no oesophageal damage.

The patient should be taken to a doctor without delay and treatment should be symptomatic and supportive.

**IDENTIFICATION:**

**BETADINE® MOUTHWASH & GARGLE** is a dark-brown solution with a characteristic odour.

**PRESENTATION:**

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

**STORAGE INSTRUCTIONS:**

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

C/16.4/142

**Export Details:**
Namibia: NS0
Registration No. 90/16.4/0098

**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

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

March 1996

**BETADINE®** is a Registered Trademark.

**SKEDULERINGSTATUS:** S0

**EIEDOMSNAAM (EN DOSEERVORM):**

**BETADINE® MOUTHWASH & GARGLE (OPLOSSING)**

**SAMESTELLING:**

Elke 100 ml bevat povidoonjodium 1,0 g (1% *m/v*) gelyk aan 0,1 % *m/v* beskikbare jodium.
Bevat 7,1% *v/v* alkohol.
Suikervry.

**FARMAKOLOGIESE KLASSIFIKASIE:**

A 16.4 Naso-faringeale antiseptika en mond-en-keelantiseptika.

**FARMAKOLOGIESE WERKING:**

Povidoonjodium is 'n multivalente breëspektrum plaaslike ontsmettingsmiddel 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:**

**BETADINE® MOUTHWASH & GARGLE** word aanbeveel vir die verligting van pynlike infeksies en ontsteekte toestande in die mond en keel, asook as 'n gereelde mondspoelmiddel.

**INFEKSIES:** Afteuse mondulkusse, tandvleisontsteking, mondontsteking en keelontsteking wat aan oppervlakkige infeksies te wyte is. Voorbehoeding gedurende en na mondoperasies.

**KONTRA-INDIKASIES:**

- Sensitiwiteit vir povidoonjodium.
- Pasiënte met hiperfunksie van die tiroïed (hipertiroïedisme), ander gemanifesteerde tiroïedsiektes (tiroïedversteuring) en nie-toksiese nodulêre kolloïdale goiter.

**WAARSKUWINGS:**

1. Moenie voor gebruik verhit nie.
2. In gevalle van velirritasie, kontakdermatitis of hipersensitiwiteit, staak gebruik.

**INTERAKSIES:**

Absorpsie van jodium van **BETADINE® MOUTHWASH & GARGLE** mag met tiroïedfunksietoetse inmeng en kan 'n beplande behandeling van die tiroïed met jodium (radio-jodiumterapie) onmoontlik maak. Aan die einde van die behandeling behoort 'n toepaslike interval toegelaat te word voordat 'n nuwe flikkergram uitgevoer word.

Gereelde of langdurige gebruik behoort vermy te word by inwonende pasiënte wat gelyktydige litiumterapie ontvang.

**SWANGERSKAP EN LAKTASIE:**

Tydens swangerskap en laktasie behoort **BETADINE® MOUTHWASH & GARGLE** slegs gebruik te word indien dit streng aangedui is, en die gebruik daarvan behoort tot 'n absolute minimum beperk te word.

Geabsorbeerde jodium kan die plasentale skans kruis en in borsmelk uitgeskei word. Alhoewel geen nadelige effekte van beperkte gebruik aangemeld is nie, word omsigtigheid aanbeveel en terapeutiese voordeel moet teen die moontlike effekte van die absorpsie op fetale tiroïedfunksie en -ontwikkeling gebalanseer word.

**DOSIS EN GEBRUIKSAANWYSINGS:**

**As mondspoel:** Verdun een deel van **BETADINE® MOUTHWASH & GARGLE** met twee dele water, spoel mond deeglik en spoeg uit, of gebruik soos voorgeskryf deur geneesheer of tandarts.

**Vir infeksies van die mond en keel:** Gebruik volsterkte, spoel of gorrel vir 30 sekondes en spoeg uit, herhaal elke uur of soos voorgeskryf deur geneesheer of tandarts.

**Vir kinders onder die ouderdom van 3 jaar:** Verdun een deel **BETADINE® MOUTHWASH & GARGLE** met drie dele water. Verf aan die mond met 'n watepluisie.

**NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:**

**Newe-effekte:**

Die volgende newe-effekte is aangemeld, maar die frekwensie is onbekend.

***Vel- en onderhuidse weefselversteurings***

Hipersensitiwiteit en plaaslike irritasie mag voorkom, byvoorbeeld urtikarie, pruritus, eriteem, klein blasies, angio-edeem of soortgelyke manifestasies.

**Spesiale Voorsorgmaatreëls:**

Indien irritasie, swelling of rooiheid voorkom, moet behandeling gestaak word en die geneesheer geraadpleeg word.

Indien ernstige of aanhoudende seer keel, of seer keel gesamentlik met hoë koors, hoofpyn, naarheid en braking voorkom, moet jy jou geneesheer dadelik raadpleeg omdat hierdie simptome 'n ernstige toestand mag aandui.

Absorpsie van povidoon-jodium mag met tiroïedfunksietoetse inmeng.

Gereelde of langdurige gebruik behoort vermy te word by pasiënte met tiroïedversteurings.

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

Indien inname sou plaasvind, sluit die simptome van akute vergiftiging 'n onaangename metaalagtige smaak, braking, abdominale pyn en diaree in. Anurie kan 1 tot 3 dae later voorkom; sirkulatoriese versaking wat tot die dood kan lei; edeem van die stemband wat versmoring kan veroorsaak; aspirasie, longontsteking of pulmonale edeem. Slukdermvernouing kan voorkom as die pasiënt die akute stadium oorleef.

Vir behandeling van akute vergiftiging, voer die pasiënt teue melk en styselpap. Maagspoeling kan onderneem word as daar geen bewys van slukdermbeskadiging is nie. Die pasiënt moet onmiddellik na 'n geneesheer geneem word en behandeling moet asimptomaties en ondersteunend wees.

**INDENTIFIKASIE:**

**BETADINE® MOUTHWASH & GARGLE** is 'n donkerbruin oplossing met 'n kenmerkende reuk.

**AANBIEDING:**

Wit of roomkleurige, ronde, hoë-digtheid poliëtileen (HDPE) 125 ml bottel, met lae-digtheid poliëtileen (LDPE) deursigtige spuit en 'n polipropileen proppie.

**BERGINGSAANWYSINGS:**

Bêre by of benede 25 °C.

HOU BUITE BEREIK VAN KINDERS.

**REGISTRASIENOMMER:**

C/16.4/142

**Uitvoer besonderhede:**
Namibië: NS0
Registrasienommer. 90/16.4/0098

**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

**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:**

Maart 1996

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

MC MWG1 125M PL ZA 01