

SCHEDULING STATUS: S2**PROPRIETARY NAME
(AND DOSAGE FORM):****BETADINE® DOUCHE
(SOLUTION)****COMPOSITION:**

Each 1 ml contains povidone-iodine 100 mg, equivalent to 10 mg available iodine.

**PHARMACOLOGICAL
CLASSIFICATION:**

A. 18.6 Vaginal Preparations

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:

1. Trichomonal, monilial, bacterial and non-specific vaginitis.
2. Cleansing and deodorising douche.

CONTRA-INDICATIONS:

Sensitivity to povidone-iodine. Patients with non-toxic nodular colloid goitre should not use povidone-iodine. This product is spermicidal and should not be used when conception is desired.

**WARNINGS AND SPECIAL
PRECAUTIONS:**

1. Not to be used by persons who are allergic to iodine.
2. Not to be used in pregnancy or by lactating women.
3. Alkalis will reduce the activity of this preparation.
4. Absorption of povidone-iodine may interfere with thyroid function tests.
5. This product is spermicidal and should not be used when conception is desired.

**DOSAGE AND DIRECTIONS
FOR USE:**

Use as **Therapeutic Douche** - Add two medicine measures (10 ml) of **BETADINE® DOUCHE** to the squeeze bottle. Fill the squeeze bottle with lukewarm water. Screw the applicator to the squeeze bottle and shake gently. Carefully insert the applicator high into the vagina without causing discomfort. Expel as much cleansing liquid as possible by applying gentle pressure on the sides of the squeeze bottle, allowing the solution to run freely from the vagina. Remove the applicator from the vagina allowing air to enter the squeeze bottle, so that it regains its original shape.

Reinsert the applicator into the vagina squeezing once again to cleanse the vagina thoroughly. Repeat until all the **BETADINE® DOUCHE** has been used. Finally rinse away the excess solution from around the vagina. Pat dry the vaginal area with a clean cloth or paper towel. Rinse clean the empty bottle and applicator in warm water and store for

further use. Use once per day for 7 – 14 days or as directed by the physician.

**Use as Cleansing and
Deodorising Douche -**

Add one medicine measure (5 ml) of **BETADINE® DOUCHE** to the squeeze bottle. Fill the squeeze bottle with lukewarm water. Use as per the instructions under **Therapeutic Douche**. Use once or twice weekly, or as directed by the physician.

SIDE-EFFECTS:

Povidone-iodine sensitivity may develop in certain individuals. If irritation, discomfort, redness, swelling or other signs of sensitivity occur, the patient should discontinue use and consult her physician.

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

Systemic effects include metabolic acidosis, hypernatraemia and renal impairment. Treatment is symptomatic and supportive.

IDENTIFICATION:

BETADINE® DOUCHE is a dark brown aqueous liquid with a floral odour.

PRESENTATION:

BETADINE® DOUCHE is available in a white or beige, polyethylene container containing 250 ml of liquid with a transparent polyethylene spout and a blue polypropylene cap. The **BETADINE® DOUCHE Kit** also contains a blue empty squeeze bottle and vaginal applicator.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

**KEEP OUT OF REACH OF
CHILDREN.****REGISTRATION NUMBER:****South Africa:**

C/18.6/143

Export details:

Namibia:	NS1
Registration No.	04/18.6/1020
Botswana:	S3
Reference No.	B9300345

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

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www.mundipharma.co.za

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

23 September 1993

BETADINE® is a Registered
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SKEDULERINGSSTATUS: **S2****EIENDOMSNAAM:
(EN DOSEERVORM)****BETADINE® DOUCHE
(OPLOSSING)****SAMESTELLING:**

Elke 1 ml bevat povidoonjodium 100 mg, gelyk aan 10 mg beskikbare jodium.

**FARMAKOLOGIESE
KLASSIFIKASIE:**

A 18.6 Vaginale preparate

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 van die samestelling. Baie virusse, protosoë, giste, siste en spore is ook vatbaar.

INDIKASIES:

1. Trigononale, moniliale, bakteriële en nie-spesifieke vaginitis.
2. As 'n reinigende en reukwerende douche.

KONTRA-INDIKASIES:

Gevoeligheid vir povidoonjodium. Pasiënte met 'n atoksiese nodulêre kolloïedkropgeswel behoort nie povidoonjodium te gebruik nie. Hierdie produk is saadselvernietigend en behoort nie gebruik te word as bevrugting verlang word nie.

**WAARSKUWINGS EN SPESIALE
VOORSORGMAATREËLS:**

1. Moet nie gebruik word deur pasiënte wat allergies is vir jodium nie.
2. Moet nie deur verwagte of borsvoedende vroue gebruik word nie.
3. Alkaleïe sal veroorsaak dat hierdie preparaat minder aktief is.
4. Povidoonjodiumabsorpsie kan met skildklierfunksie-toetse inmeng.
5. Hierdie produk is saadselvernietigend en behoort nie gebruik te word as bevrugting verlang word nie.

DOSIS EN**GEBRUIKSAANWYSINGS:**As 'n **Terapeutiese Douche**:

Voeg twee medisynemate (10 ml) **BETADINE® DOUCHE** in die drukbottel. Vul die drukbottel met loutwarm water.

Skroef die toediener aan die drukbottel en skud sagkens. Plaas die toediener versigtig en hoog in die vagina sonder om ongemak te veroorsaak. Druk soveel van die vloeistof as moontlik uit, deur die bottel ligtelik te druk. Laat die vloeistof vrylik uit die vagina loop. Verwyder die toediener van die vagina en laat lug in die drukbottel sodat dit terugkeer na oorspronklike vorm. Plaas die toediener weer in die vagina en druk die bottel om die vagina deeglik skoon te maak. Herhaal tot al die **BETADINE® DOUCHE** gebruik is. Spoel die oorskiet vloeistof af rondom die vaginale area. Druk die vaginale area droog met 'n skoon lap of papierhanddoek. Spoel die drukbottel en toediener met warm water en bêre vir toekomstige

gebruik. Gebruik een keer per dag vir 7 – 14 dae of soos deur u geneesheer aangedui.

As 'n **Reinigende en Reukwerende Douche**:

Voeg een medisynemate (5 ml) **BETADINE® DOUCHE** in die drukbottel. Vul die drukbottel met loutwarm water en gebruik soos aangedui onder **Terapeutiese Douche**. Gebruik een of twee keer per week, of soos deur u geneesheer aangedui.

NEWE-EFFEKTE:

Sommige persone kan sensitiwiteit vir povidoonjodium ontwikkel. Indien irritasie, ongemak, rootheid, swelling of enige ander tekens van sensitiwiteit opgemerk word, moet die pasiënt die gebruik van die middel staak en haar geneesheer raadpleeg.

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

Sistemiese gevolge sluit metaboliese asidose, hipernatremie en nierversaking in. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

BETADINE® DOUCHE, is 'n donkerbruin waterige vloeistof met 'n reuk van blomme.

AANBIEDING:

BETADINE® DOUCHE is beskikbaar in 'n wit of roomkleurige, poliëtileen bottel wat 250 ml oplossing bevat, met 'n deurskynende poliëtileen spuit en 'n blou polipropileen prop. Die **BETADINE® DOUCHE toestel** bevat ook 'n leë blou drukbottel en vaginale toediener.

BERGINGSANWYSINGS:

Bêre by of benede 25 °C.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:**Suid Afrika:**

C/18.6/143

Uitvoer besonderhede:

Namibië: **NS1**
 Registrasie Nr. 04/18.6/1020
 Botswana: **S3**
 Verwysingsnommer: B9300345

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

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**DATUM VAN PUBLIKASIE VAN
HIERDIE VOUBILJET:**

23 September 1993

BETADINE® is 'n geregistreerde handelsmerk.