

**SCHEDULING STATUS:**

S1

**PROPRIETARY NAME (AND DOSAGE FORM):**

CLOTRIMAZOLE BIOTECH VAGINAL (cream)

**COMPOSITION:***Each 1 g of cream contains:*

Clotrimazole 10mg

*Preservatives:*

Nipastat 0,275 % (m/m)

Imidurea 0,300 % (m/m)

*Inactive ingredients:* propylene glycol, liquid paraffin, cremophor A25, cremophor A6, cetostearyl alcohol.**PHARMACOLOGICAL CLASSIFICATION:**

A 20.2.2 Fungicides

**PHARMACOLOGICAL ACTION:**

CLOTRIMAZOLE BIOTECH VAGINAL cream is a broad spectrum antimycotic with fungicidal properties.

**INDICATIONS:**

For the relief of vaginal itching, burning and discharge associated with recurrent vaginal yeast infections (Vaginal candidiasis).

**CONTRA-INDICATIONS:**

Possible sensitivity to clotrimazole.

The possibility of absorption of clotrimazole when administered vaginally cannot be excluded.

**WARNINGS AND SPECIAL PRECAUTIONS:**

- Use only if you have already had a vaginal yeast infection diagnosed by a medical practitioner and you have the same symptoms now, otherwise consult your doctor. These symptoms include itching and burning of the vagina and sometimes a white discharge.
- If there is no improvement in three days or if symptoms have not disappeared within seven days, then consult a medical practitioner as not all vaginal infections are caused by yeasts.
- Consult a medical practitioner if you have abdominal pain, fever or a foul-smelling vaginal discharge before or during use of this medication.
- If symptoms recur within two months, consult a medical practitioner.
- If you are pregnant or think you may be pregnant or are nursing, do not use this medication except on the advice of a medical practitioner.
- Do not use in girls under 12 years of age, except on the advice of a medical practitioner.
- If skin rash or new irritation occurs, discontinue use.

**DOSAGE AND DIRECTIONS FOR USE:**

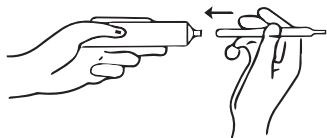
Fill enclosed vaginal applicator to the top (i.e. 5 g CLOTRIMAZOLE BIOTECH VAGINAL cream). Insert deeply into the vagina every night on retiring for six (or 7) consecutive nights even during menstruation and even if symptoms disappear. This is best achieved when lying on the back with the legs pulled in a little towards the body. If individual cases should require it, two applications of 5 g vaginal cream can be used daily, i.e. one in the morning and one in the evening, for 6 - 12 days.

For Candida vulvitis or vulvo-vaginitis the vaginal cream should be applied thinly to the external genitalia 2 - 3 times a day for 1 - 2 weeks.

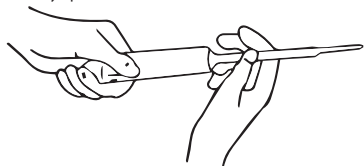
For the prevention of re-infection, the partner should be treated locally with clotrimazole cream at the same time. This preparation does not stain the underwear.

**DIRECTIONS FOR USING THE APPLICATOR:***Preparation of the applicator:*

1. Wash hands thoroughly.
2. Screw the open end of one of the applicators over the opening of the tube of cream.



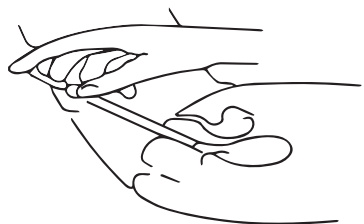
3. Gently squeeze the bottom of the tube so that the cream fills the applicator to the top, pushing the plunger out to almost its full extent.



4. Unscrew the tube of cream and replace its cap.

*Inserting the applicator:*

5. Carefully insert the end of the applicator as deeply as possible into the vagina. (Making sure the plunger does not fall out). This is best achieved when lying on the back with the legs pulled in a little towards the body.



6. Slowly push the plunger with the forefinger until it stops.
7. Remove the applicator from the vagina and discard it.

*Each applicator is for single use only:*

The surplus cream may be used to treat any Inflammation of the vulva (outer vaginal area) and nearby areas. The cream should be applied thinly and rubbed in gently two to three times a day.

**SIDE-EFFECTS:**

Local reactions including irritation and burning may occur. Contact allergic dermatitis has been reported. In case of systemic absorption, lower abdominal cramps, increase in urinary frequency or skin rash may occur.

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

See SIDE-EFFECTS. In case of accidental ingestion, gastro-intestinal disturbances and central nervous system depression may occur. Treatment is symptomatic and supportive.

**IDENTIFICATION:**

A soft white cream.

**PRESENTATION:**

Tubes of 50 g with 6 or 8 applicators in a carton.

**STORAGE INSTRUCTIONS:**

Store at or below 25 °C in a well closed container, protected from light.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

27/20.2.2/0338

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

Biotech Laboratories (Pty) Ltd  
Ground Floor, Block K West, Central Park  
400 16<sup>th</sup> Road, Randjespark, Midrand, 1685  
South Africa

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

15 February 1998

**SKEDULERING STATUS:**

S1

**EIENDOMSNAAM (EN DOSSEERVORM):**

CLOTRIMAZOLE BIOTECH VAGINAL (room)

**SAMESTELLING:***Elke 1 g room bevat:*

Klotrimasool 10 mg

*Preserveermiddels:*

Nipastat 0,275 % (m/m)

Imidurea 0,300 % (m/m)

*Onaktiewe bestandele:* propileenglikol, vloeibare paraffien, cremophor A25, cremophor A6, cetostearyl alkohol.**FARMAKOLOGIESE KLASSIFIKASIE:**

A20.2.2 Swamdoders

**FARMAKOLOGIESE WERKING:**

Clotrimazole Biotech Vaginal room is 'n breë spectrum antimikotikum met swamdodende eienskappe.

**INDIKASIES:**

Vir die verligting van vaginale jeuk, branderigheid en afskeiding geassosieër met herhalende vaginale swam infeksies. (Vaginale kandidiase)

**KONTRA-INDIKASIES:**

Moontlike sensitiviteit teen klotrimasool.

Die moontlikheid van absorpsie wanneer klotrimasool toegedien word, kan nie uitgesluit word nie.

**WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS:**

- Gebruik slegs wanneer daar reeds voorheen 'n vaginal swam infeksie deur 'n mediese praktisyn by u gediagnoseer is en u dieselfde simptome nou ervaar, anders moet u 'n dokter besoek. Hierdie simptome sluit jeuk en brand van die vagina in, en soms 'n wit afskeiding.
- Indien daar geen verbetering is binne 3 dae van aanvang van gebruik nie, of as simptome nie binne 7 dae verdwyn nie, moet 'n mediese praktisyn gekonsulteer word, aangesien nie alle vaginale infeksies deur swamme veroorsaak word nie.
- Besoek 'n mediese praktisyn indien abdominale pyn, koors of afskeiding met 'n slegte reuk voorkom, voor of na die gebruik van hierdie medikasie.
- Indien simptome weer binne 2 maande voorkom, moet 'n mediese praktisyn gekonsulteer word.
- Indien u swanger is, of vermoed u is swanger, of borsvoed, moet u nie hierdie medikasie gebruik nie, tensy aanbeveel deur 'n mediese praktisyn.
- Moet nie gebruik word in meisies onder die ouderdom van 12 jaar nie, buiten op aanbeveling van 'n mediese praktisyn.
- Indien veluitslag of nuwe irritasie voorkom, staak gebruik.

**DOSIS EN GEBRUIKSAANWYSINGS:**

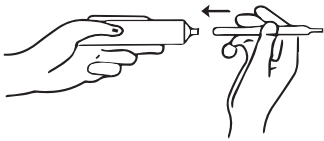
Vul die ingeslote toediener tot bo (i.e. 5 g CLOTRIMAZOLE BIOTECH VAGINAL room). Plaas die toediener diep binne- in die vagina saans voor slaapyd vir ses (of 7) agtereenvolgende aande, selfs gedurende menstruasie en selfs wanneer simptome verdwyn. Toediening is beter wanneer plat op die rug gelê word, met bene ingetrek na die liggaam. Indien individuele gevalle dit benodig, kan twee toedienings van 5 g vaginale room daaglik gebruik word, i.e. een in die oggend en een in die aand, vir 6 – 12 dae.

Vir Candida vulvitis of vulvo-vaginitis, moet die vaginale room dun aan die eksterne genitalia aangewend word, 2-3 keer per dag vir 1-2 weke.

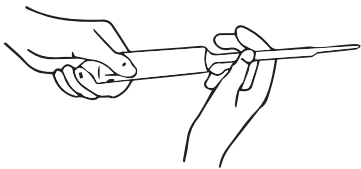
Vir voorkoming van herinfeksie, moet die eggenoot terselfertyd lokaal met klotrimasool room behandel word. Hierdie preparaat veroorsaak nie vlekke op onderklere nie.

**AANWYSINGS VIR DIE GEBRUIK VAN DIE TOEDIENER:***Voorbereiding van die toediener:*

1. Was hande deeglik.
2. Skroef die oop punt van een van die toedieners oor die opening van die buis room.



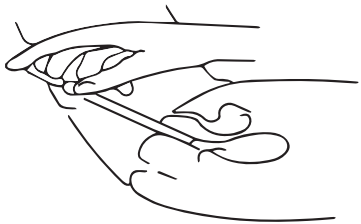
3. Druk die basis van die buis versigtig, sodat die plunjer die toediener byna tot bo met room vul.



4. Skroef die buis room uit die toediener en plaas die skroefprop terug.

*Plaas die toediener in:*

5. Plaas die toediener versigtig tot so diep moontlik in die vagina. (Maak seker die plunjer val nie uit nie). Die beste resultaat word verkry wanneer op die rug gelê word, met bene effens na die liggaam opgetrek.



6. Druk die plunjer stadig met die wysvinger totdat dit stop.

7. Verwyder die toediener uit die vagina en gooi dan weg.

*Elke toediener is slegs vir enkel gebruik:*

Die oorblywende room in die buis kan gebruik word om enige inflammasie van die vulva (buitenste vaginale area) en nabygeleë gebiede te behandel. Die room moet dun aangewend word en liggies twee tot drie keer per dag in gevryf word.

**NEWE-EFFEKTE:**

Lokale reaksies insluitend irritasie en branderigheid mag voorkom. Kontak allergiese dermatitis is al aangemeld. Ingeval van sistemiese absorpsie mag lae abdominale krampe, verhoging van urinêre frekwensie of veluitslag voorkom.

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

In geval van toevallige ingestie, kan gastro-intestinale verstourings en sentrale senuwee sisteem onderdrukking voorkom. Behandeling is simptomaties en ondersteunend.

**IDENTIFIKASIE:**

'n Sagte wit room

**AANBIEDING:**

'n 50 g Buis met 6 of 8 vaginale toedieners in n karton.

**BERGINGSINSTRUKSIES:**

Bewaar teen of benede 25°C in 'n dig geseelde houer, beskerm teen lig.

HOU BUITE BEREIK VAN KINDERS.

**REGISTRASIE NOMMER:**

27/20.2.2/0338

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

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**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:**

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