SCHEDULINGSTATUS: S1

PROPRIETARY NAME: (AND DOSAGE FORM):
INNOSPORE Cream

COMPOSITION:
Each 1 g of cream contains:

Clotrimazole	10 mg
Preservative: Nipastat	0.275 % m/m

PHARMACOLOGICAL CLASSIFICATION:
A 20.2.2 Fungicides

PHARMACOLOGICAL ACTION:
INNOSPORE 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)

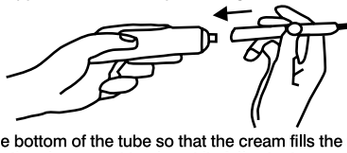
CONTRA-INDICATIONS:
Possible sensitivity to clotrimazole. The possibility of absorption of clotrimazole when administered vaginally cannot be excluded. Safe use during pregnancy has not been established.

WARNINGS:
1. Use only if you have previously 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.
2. If there is no improvement within 3 days or if symptoms persist for 7 days, consult your doctor.
3. Consult your doctor if you have abdominal pain, fever or a foul smelling vaginal discharge before or during use of this medication.
4. If symptoms recur within 2 months consult your doctor.
5. If you are or may be pregnant or nursing, do not use this medication except on the advice of your doctor.
6. Not for use by girls under 12 years unless on medical advice.
7. If skin rash or new irritation occurs, discontinue use.
8. Direct contact with **INNOSPORE** cream may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.

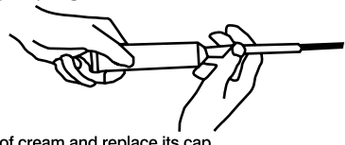
DOSAGE AND DIRECTIONS FOR USE:
Fill enclosed vaginal applicator to the top (i.e. 5 g **INNOSPORE** cream). Insert deeply into the vagina every night on retiring for six consecutive days. This is best achieved when lying on the back with the legs pulled in a little towards the body. If individual cases should require it, two applications of 5 g **INNOSPORE** cream can be used daily, i.e. one in the morning and one in the evening, for 6 - 12 days. The treatment should not be carried out during menstruation but should be completed before this begins. For Candida vulvitis or vulvo-vaginitis apply the **INNOSPORE** cream thinly to the external genitalia 2 or 3 times a day for 1 to 2 weeks. For the prevention of re-infection the partner should be treated locally with **INNOSPORE** cream at the same time. This preparation does not stain the underwear.

DIRECTIONS FOR USING THE APPLICATOR

PREPARATION OF THE APPLICATOR
1. Wash your hands thoroughly.
2. Screw the open end of the applicator over the opening of the tube of cream. The plunger of the applicator should be pushed right in at this stage.

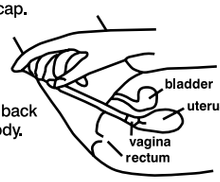


3. Gently squeeze the bottom of the tube so that the cream fills the applicato to the top, pushing the plunger out to almost its full extent.



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 (ensure plunger does not fall out). This is the 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 rinse thoroughly or discard.

EACH APPLICATOR IS ONLY USED ONCE.

8. Surplus cream may be used to treat any inflammation of the vulva (outer vaginal area) and nearby areas. In this case the cream should be applied thinly and rubbed in gently 2 - 3 times a day.

Follow your doctor's instructions.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Local reactions including irritation and burning may occur. Contact allergic dermatitis has been reported. If this occurs stop the treatment. **INNOSPORE** cream must be used only under medical supervision in pregnancy, especially in the earlier stages. In case of systemic absorption, lower abdominal cramps, an increase in urinary frequency or skin rash may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
See "side effects and special precautions". In case of accidental ingestion, gastro-intestinal disturbances and central nervous system depression may occur. Treatment is symptomatic and supportive.

IDENTIFICATION:
Soft white cream.

PRESENTATION:
Boxed tube of 50 g with 6 vaginal applicators.

STORAGE INSTRUCTIONS:
Store at or below 25 °C.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
27/20.2.2/0068

NAME AND BUSINESS ADDRESS OF THE APPLICANT:
Innovata Pharmaceuticals (Pty) Ltd.
Crownwood Office Park, Block D
100 Northern Parkway
Ormonde
Johannesburg
2091
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
1 October 1992

PI/INNOS50/001

LAB325(1)

SKEDULERINGSTATUS: S1

EIENDOMSNAAM (EN DOSEERVORM):
INNOSPORE Room

SAMESTELLING:
Elke 1 g room bevat:

Klotrimasool	10 mg
Preserveermiddel: Nipastat	0,275 % m/m

FARMAKOLOGIESE KLASSIFIKASIE:
A 20.2.2 Swamdoders

FARMAKOLOGIESE WERKING:
INNOSPORE room is 'n breë-spektrum antimikotiese middel met swamdodende eienskappe.

INDIKASIES:
Vir die verligting van vaginale jeukerigheid, branderigheid en afskyding wat geassosieer word met herhaaldelike vaginale gisinfeksies (vaginale kandidiase).

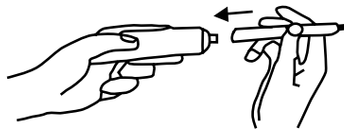
KONTRA-INDIKASIES:
Moontlike gevoeligheid vir klotrimasool. Die moontlikheid dat klotrimasool geabsorbeer kan word gedurende vaginale toediening kan nie uitgesluit word nie. Veiligheid gedurende swangerskap is nog nie vasgestel nie.

WAARSKUWINGS:
1. Gebruik slegs indien 'n vaginale gisinfeksie voorheen deur 'n geneesheer by u gediagnoseer is en u nou dieselfde simptome ondervind. Indien nie, raadpleeg u geneesheer. Hierdie simptome sluit jeukerigheid en branderigheid van die vagina in en soms ook 'n wit afskeiding.
2. Indien daar geen verligting na 3 dae is nie of die simptome nog nie na 7 dae verdwyn het nie, raadpleeg u geneesheer aangesien nie alles vaginale infeksies deur giste veroorsaak word nie.
3. Raadpleeg u geneesheer indien u buikpyn, koors of 'n slegruikende vaginale afskeiding voor of gedurende die gebruik van hierdie medikasie ondervind.
4. Indien die simptome binne 2 maande terugkeer, raadpleeg u geneesheer.
5. Indien u swanger is of vermoed dat u moontlik swanger is of indien u borsvoed, moet u nie hierdie medikasie gebruik nie tensy deur 'n geneesheer voorgeskryf.
6. Vermy gebruik in meisies onder die ouderdom van 12 jaar, tensy deur 'n geneesheer voorgeskryf.
7. Indien 'n veluitslag of 'n nuwe irritasie voorkom, staak gebruik.
8. Direkte kontak met **INNOSPORE** room mag die doeltreffendheid van lateks produkte soos kondome en diafragmas verminder. Die effek is tydelik en kom slegs gedurende behandeling voor.

DOSIS EN GEBRUIKSAANWYSINGS:
Maak ingeslote vaginale toediener vol (d.w.s. 5 g **INNOSPORE** room). Steek diep in die vagina elke aand met slapenstyd vir ses agtereenvolgende dae. Dit kan die beste gedoen word deur op die rug te lê met die bene effens na die liggaam ingetrek. Indien individuele gevalle dit vereis, kan twee vaginale toedienings van 5 g **INNOSPORE** room daagliks gebruik word, d.w.s. een in die oggend en een in die aand, vir 6 -12 dae. Die behandeling moet nie gedurende menstruasie toegepas word nie, maar moet voor die aanvang daarvan voltooi word. Vir Candida vulvitis of vulvo-vaginitis moet die **INNOSPORE** room vir 1 - 2 weke 2 tot 3 maal per dag aan die buitenste genitalieë dun aangewend word. Vir die voorkoming van herinfeksie behoort die man terselfdetyd plaaslik met **INNOSPORE** room behandel te word. Dit vlek nie die onderklere nie.

AANWYSINGS VIR DIE GEBRUIK VAN DIE TOEDIENER:

VOORBEREIDING VAN TOEDIENER
1. Was hande deeglik.
2. Plaas die oop kant van die toediener oor die opening van die roombuis, en skroef dit vas. Die suier van die toediener moet op dié stadium heeltemal ingedruk wees.

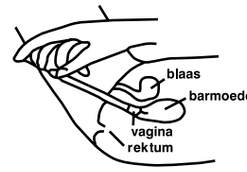


3. Druk die onderent van die buis sodat die room die toediener heeltemal vul en sodoende die suier so ver as moontlik uitdruk.



4. Verwyder die roombuis en maak dit toe.

INPLASING VAN TOEDIENER
5. Druk die end van die toediener versigtig so diep as moontlik in die vagina in (maak seker dat die suier nie uitgly nie). Dit kan die beste as volg gedoen word. Lê op die rug met die bene effens na die liggaam ingetrek.
6. Druk die suier stadig heeltemal in met die voorvinger.



7. Verwyder die toediener van die vagina en gooi weg of spoel af.

ELKE TOEDIENER WORD EEN KEER GEBRUIK

8. Die oortollige room mag vir behandeling van enige ontsteking van die vulva (buite-vaginale dele) en omliggende oppervlaktes gebruik word. 'n Dun laag van die room moet aangewend en versigtig ingevryf word 2 - 3 ker per dag.

Volg u dokter se voorskrif.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:
Lokale reaksies wat irritasie en branderigheid insluit kan voorkom. Kontakallergiedermatitis is gerapporteer. **INNOSPORE** room behoort slegs onder mediese advies aan swanger vroue toegedien word, veral in die vroeë stadium van swangerskap. Onderbuikse krampe, toename in urinêre frekwensie of veluitslag kan voorkom in die geval van sistemiese absorbering.

BEKENDE SIMPTOME VAN OORDOSERING EN BEHANDELING DAARVAN:
Sien "newe-effekte en spesiale voorsorgmaatreëls". In die geval van toevallige inname kan maagdermsteurnisse en sentrale senustelsel depressie voorkom. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
'n Wit sagte room.

AANBIEDING:
Kartonhouer en buis van 50 g met 6 vaginale toedieners.

BERGINSVOORSKRIFTE:
Bewaar onder of teen 25 °C.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
27/20.2.2/0068

NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT:
Innovata Pharmaceuticals (EDMS) Bpk
Crownwood Kantoorpark, Blok D
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2091
Suid-Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
1 Oktober 1992

PI/INNOS50/001

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