Patient Information Leaflet

SCHEDULING STATUS: S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM.

Contains 10 mg clotrimazole per 1 g of cream.

WHAT CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM CONTAINS

The active substance in each 1 gram of cream is clotrimazole 10 mg.

The preservative is Nipastat (0,275 % m/m).

The other ingredients are cetostearyl alcohol, cremophor A6, cremophor A25, imidurea, liquid paraffin, propylene glycol, purified water.

WHAT CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM IS USED FOR

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM is used to treat vaginal thrush (candidiasis) or other fungal infections that a medical doctor has previously diagnosed. The symptoms of vaginal thrush are usually vaginal itching, burning and discharge.

BEFORE YOU USE CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

Do not use CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM:

- If you are hypersensitive (allergic) to clotrimazole or any of the other ingredients of CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM.

Take special care with CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM:

- You should only use CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM if you have the same symptoms of vaginal infection (itching, burning, sometimes white discharge) that a doctor has diagnosed previously.
- If you are pregnant or breastfeeding, you should only use CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM on the advice of your doctor.

- If your symptoms does not improve after 3 days or disappear after 7 days after starting to use CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM, speak to your doctor as you may have a different kind of vaginal infection that is not caused by yeasts or may be a sign of other conditions, such as diabetes or impaired immune function.
- If you get the same symptoms within two months of treatment, speak to your doctor.
- If you get a skin rash or new irritation, stop using CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM and speak to your doctor.
- CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM may reduce the effectiveness of latex contraceptives like condoms and diaphragms. You should use additional contraceptive precautions up to three days after using this product.
- Do not use tampons or other vaginal products while using CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM.

Pregnancy and Breastfeeding

If you are pregnant or think that you may be pregnant or if you are breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM. CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM may be used during the second and third trimesters of pregnancy on the advice of a medical doctor.

Driving and using machinery

It is not likely that the use of CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM will have any effect on your ability to drive or use machines.

Important information about some of the ingredients of CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM.

This product contains cetostearyl alcohol which may cause local skin irritation (e.g. rash, itching or redness).

Using other medicines with CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

Always tell your healthcare professional if you are taking any other medicine.

If you are taking/using other medicines on a regular basis, including complementary or traditional medicines, the use of CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO USE CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

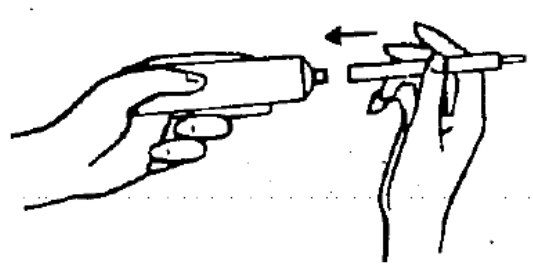
Do not share medicines prescribed for you with any other person.

The cream should be administered vaginally using the applicators supplied. The usual dose for women and children 12 years and older is one dose (5 g) every night for 6 consecutive days. The dose can be increased to twice daily, i.e. in the morning and evening, for 6 to 12 days. Please follow the instructions for use below.

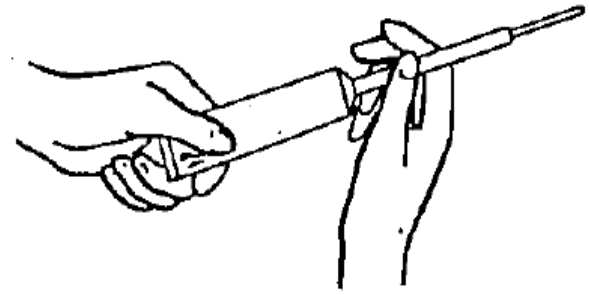
INSTRUCTIONS FOR USE

Preparation of the applicator:

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



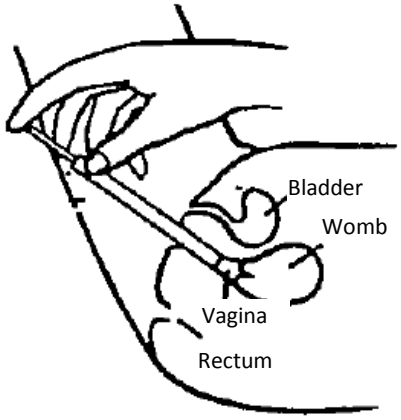
3. Gently squeeze the bottom of the tube so that the cream fills the applicator to the top, pushing the plunger out to almost its full extent.



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

Inserting the applicator:

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



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

EACH APPLICTOR IS FOR SINGLE USE ONCE ONLY. The remaining 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 2 to 3 times a day.

It is normal for a small amount of cream to leak from the vagina after use. It does not normally stain underwear but it may be helpful to wear a panty liner.

To help prevent reinfection, you may benefit by wearing loose clothing and cotton underwear and to avoid washing with perfumed soaps and bath products.

If you use more CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM than you should

In the event of an overdose or if you accidentally swallow CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital.

If you forget to use a dose of CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

If you forgot to use CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM, use it as soon as you remember, but not if it is almost time for your next dose.

Do not use a double dose to make up for forgotten individual doses.

Effects when treatment with CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM is stopped

You should follow the instructions and complete the full course even if your symptoms have improved or if menstruation begins. This may help to prevent the infection from recurring.

POSSIBLE SIDE EFFECTS

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM can have side effects.

Stop using CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM immediately and speak to your doctor if you have any of the following symptoms:

- An allergic reaction that can include swelling of the lips, throat, face, hands and feet and sometimes difficulty in breathing or swallowing.
- A skin rash around the site of application
- Vaginal burning, itching, discharge, or other irritation not present before therapy

You may also experience other side effects and you should tell your doctor if they continue or are bothersome:

- Stomach cramps or pain
- The need to urinate more often than usual
- Headache
- Burning or irritation of the penis of your sexual partner

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

Store all medicines out of reach of children.

Store at or below 25 °C

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

50 g aluminium tube with white plastic screw cap plus 6 vaginal applicators.

IDENTIFICATION OF CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

Soft white cream.

REGISTRATION NUMBER/REFERENCE NUMBER

27/20.2.2/0125

NAME AND ADDRESS OF REGISTRATION HOLDER

Phyto OTC Health (Pty) Ltd.

49 New Road

Midrand

1685

DATE OF PUBLICATION

20 January 2020 25735D03

Pasiëntinligtingsblad

SKEDULERINGSTATUS: S1

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM.

Bevat 10 mg klotrimasool per 1 g room.

WAT CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM BEVAT

Die aktiewe bestanddeel in elke 1 gram room is 10 mg klotrimasool.

Die preserveermiddel is Nipastat (0,275 % *m/m*).

Die ander bestanddele is ketostearielalkohol, cremophor A6, cremophor A25, imidureum, mineraalolie, propileenglikol, gesuiwerde water.

WAARVOOR CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM GEBRUIK WORD

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM word gebruik om vaginale sproei (kandidiase) of ander swaminfeksies wat ’n dokter al voorheen gediagnoseer het, te behandel. Die simptome van vaginale sproei is gewoonlik vaginale gejeuk, brandgevoel en afskeiding.

VOORDAT JY CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM GEBRUIK

Moenie CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM gebruik nie:

- Indien jy hipersensitief (allergies) is vir klotrimasool of vir enige van die ander bestanddele van CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM.

Wees versigtig met CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM:

- Jy moet slegs CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM gebruik indien jy dieselfde simptome van ’n vaginale infeksie het as wat al voorheen deur ’n dokter gediagnoseer is (gejeuk, brandgevoel, soms ’n wit afskeiding).
- Indien jy swanger is of jou baba borsvoed, moet jy alleenlik CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM gebruik indien jou dokter gesê het jy moet.

- Indien jou simptome nie binne 3 dae verbeter of verdwyn binne 7 dae nadat jy begin het om CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM te gebruik nie, bespreek dit met jou dokter want jy kan ’n ander soort vaginale infeksie hê wat nie deur ’n swam (gis) veroorsaak word nie of dit kan ’n teken van ’n ander toestand wees, soos diabetes of belemmerde immuunfunksie.
- Indien jy binne twee maande na behandeling dieselfde simptome kry, bespreek dit met jou dokter.
- Indien jy ’n veluitslag of nuwe irritasie kry, hou op om CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM te gebruik en bespreek dit met jou dokter.
- CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM mag die doeltreffendheid van lateks kontraseptiewe apparate soos kondome en diafragmas verlaag. Jy moet bykomende kontraseptiewe voorsorgmaatreëls neem vir tot drie dae nadat hierdie produk gebruik is.
- Moenie tampons of ’n ander vaginale produk terselfdertyd as CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM gebruik nie.

Swangerskap en borsvoeding

Indien jy swanger is, vermoed dat jy swanger mag wees of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige voordat jy CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM gebruik.

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM kan tydens die tweede en derde trimesters van swangerskap gebruik word, indien ’n mediese dokter dit so aangedui het.

Bestuur en die gebruik van masjiene

Dit is onwaarskynlik dat die gebruik van CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM enige effek op jou vermoë om ’n voertuig te bestuur en masjiene te gebruik sal hê.

Belangrike inligting oor party van die bestanddele van CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

Hierdie produk bevat ketostearielalkohol, wat plaaslike velirritasie kan veroorsaak (bv. uitslag, gejeuk of rooiheid).

Die gebruik van ander medisyne saam met CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

Sê altyd vir jou gesondheidsorgdeskundige indien jy enige ander medisyne neem.

Indien jy ander medisyne op ’n gereelde grondslag neem/gebruik, insluitende komplementêre of tradisionele medisynes, mag die gebruik van CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM saam met hierdie medisyne ongewenste wisselwerking hê. Raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige.

HOE OM CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM TE GEBRUIK

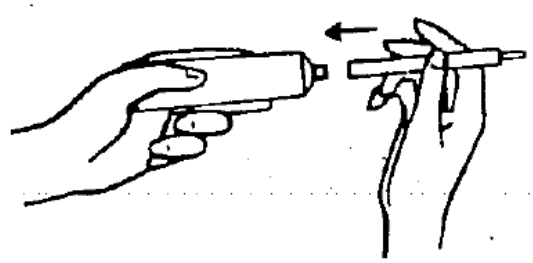
Moenie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie.

Die room moet vaginaal aangewend word deur gebruik te maak van die toedieners wat verskaf word. Die gebruiklike dosis vir vrouens en kinders van 12 jaar en ouer is een dosis (5 g) elke nag vir 6 opeenvolgende nagte. Die dosis kan verhoog word na twee keer per dag, d.i. soggens en saans, vir 6 tot 12 dae. Volg asseblief die gebruiksaanwysings hier onder.

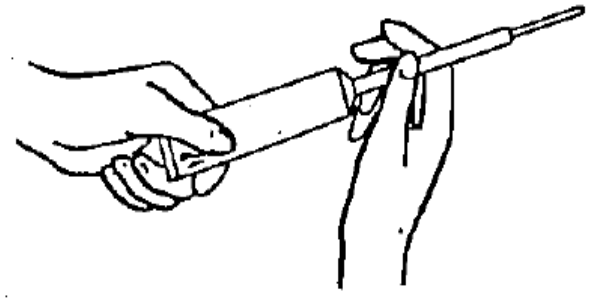
GEBRUIKSAANWYSINGS

Voorbereiding van die toediener:

1. Was jou hande deeglik.
2. Skroef die oop kant van een van die toedieners oor die opening van die buisie room. Die toediener se plunjer moet op hierdie stadium heeltemal ingedruk wees.



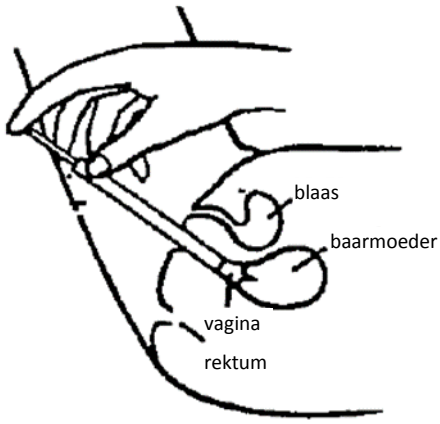
3. Druk die buisie liggies aan die onderkant sodat die room die toediener tot by die bopunt vol maak, en die plunjer feitlik tot sy volle lengte uitgedruk word.



4. Skroef die buisie room weer af en plaas die doppie terug.

Inplasing van die toediener:

1. Stoot die punt van die toediener versigtig so diep as moontlik in die vagina in (maak seker dat die plunjer nie uitval nie). Die beste manier om dit te doen is om op jou rug te lê met die bene effens opgetrek na jou lyf.



2. Druk die plunjer stadig met jou voorvinger totdat dit stop.
3. Verwyder die toediener uit die vagina en gooi dit weg.

ELKE TOEDIENER IS SLEGS BEDOEL OM EEN KEER GEBRUIK TE WORD. Die oorblywende room kan gebruik word om enige ontsteking van die vulva (buitenste vaginale area) en omliggende dele te behandel. ’n Dun lagie room kan 2 tot 3 keer per dag liggies ingevryf word.

Dit is normaal dat ’n klein hoeveelheid van die room na gebruik uit die vagina lek. Gewoonlik vlek dit nie die onderklere nie, maar die kan help om ’n dun sanitêre doekie te dra.

Dit kan voordelig wees om lospassende klere en katoenonderklere te dra, en om dit te vermy om met geparfumeerde sepe en badprodukte te was, om herinfeksie te help voorkom.

Wat om te doen indien jy meer CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM gebruik het as wat jy moet

In die geval van ’n oordosis of as jy per ongeluk CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM ingesluk het, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, verkry hulp by die naaste hospitaal.

Indien jy vergeet om ’n dosis CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM te gebruik

Indien jy vergeet om CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM te gebruik, gebruik dit sodra jy onthou, maar nie indien dit al amper tyd is vir jou volgende dosis nie.

Moenie ’n dubbele dosis gebruik om te vergoed vir die individuele dosisse wat oorgeslaan is nie.

Effek wanneer behandeling met CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM gestaak word

Jy moet die aanwysings volg en die hele kursus voltooi, selfs al het jou simptome verbeter of indien jy begin menstrueer. Dit mag help om te keer dat die infeksie herhaal.

MOONTLIKE NEWE-EFFEKTE

CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM kan newe-effekte hê.

Hou onmiddellik op om CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM te gebruik en bespreek dit met jou dokter indien jy enige van die volgende simptome het:

- ’n Allergiese reaksie wat swelling van die lippe, keel, gesig, hande en voete, en soms probleme om asem te haal of te sluk, kan insluit.
- ’n Veluitslag om die plek waar dit toegedien is.
- Vaginale brandgevoel, gejeuk, afskeiding, of ’n ander irritasie wat nie teenwoordig was voordat die terapie begin is nie.

Jy mag ook ander newe-effekte ondervind en jy moet jou dokter inlig indien dit aanhou of lastig raak:

- Maagkrampe of -pyn.
- ’n Meer gereelde behoefte om te urineer as gewoonlik.
- Hoofpyn.
- Brandgevoel of irritasie van jou geslagsmaat se penis.

Nie alle newe-effekte wat vir hierdie medisyne gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy hierdie medisyne gebruik, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgdeskundige.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

BERGING EN WEGDOENING VAN CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

Bêre alle medisyne buite bereik van kinders.

Bêre by of onder 25 °C.

Moenie gebruik ná die vervaldatum wat op die etiket voorkom nie.

Neem alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

AANBIEDING VAN CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

50 g aluminiumbuis met wit plastiekskroefprop plus 6 vaginale toedieners.

IDENTIFIKASIE VAN CLOTRIMAZOLE VAGINAL CREAM DIS-CHEM

Sagte wit room.

REGISTRASIENOMMER

27/20.2.2/0125

NAAM EN ADRES VAN DIE REGISTRASIEHOUER

Phyto OTC Health (Edms.) Bpk.

New Road 49

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1685

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