FUNGISTOP TOPICAL

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S1

FUNGISTOP TOPICAL 1 % *m/m* cream
Clotrimazole

Read all of this leaflet carefully because it contains important information for you

- FUNGISTOP TOPICAL is available without a doctor's prescription for you to treat a mild illness. Nevertheless, you still need to use FUNGISTOP TOPICAL carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share FUNGISTOP TOPICAL with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What FUNGISTOP TOPICAL is and what it is used for
2. What you need to know before you use FUNGISTOP TOPICAL
3. How to use FUNGISTOP TOPICAL
4. Possible side effects
5. How to store FUNGISTOP TOPICAL
6. Contents of the pack and other information

1. What FUNGISTOP TOPICAL is and what it is used for

The active substance in FUNGISTOP TOPICAL is clotrimazole. Clotrimazole belongs to a group of medicines called azoles and is an antifungal medicine which fights the cause of fungal skin infections.
FUNGISTOP TOPICAL is used to treat fungal skin infections such as ringworm, athlete's foot, pityriasis versicolor (causing patches of dicoloured skin) and fungal infections of the tissues adjacent to the nail of a finger or toe. It is also used to relieve irritation of the vulva (external thrush) or the end of the penis, which may be associated with thrush.

2. What you need to know before you use FUNGISTOP TOPICAL

Do not use FUNGISTOP TOPICAL:

If you are hypersensitive (allergic) to clotrimazole or any of the other ingredients of FUNGISTOP TOPICAL (listed in section 6).

Warnings and precautions

Take special care with FUNGISTOP TOPICAL:

- Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with FUNGISTOP TOPICAL burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.
- FUNGISTOP TOPICAL may reduce the effectiveness and safety of latex (rubber) products such as condoms and diaphragms (method of contraceptive). If you are using FUNGISTOP TOPICAL cream on the vulva or penis, you should use alternative precautions for at least five days after using this product.
- FUNGISTOP TOPICAL is for external use only and is not intended for ophthalmic use.

Other medicines and FUNGISTOP TOPICAL

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using FUNGISTOP TOPICAL cream.
Safety and efficacy of FUNGISTOP TOPICAL in pregnancy and breastfeeding have not been established.
No human studies on fertility have been performed.

Driving and using machines

FUNGISTOP TOPICAL has no or negligible influence on your ability to drive a vehicle or use machinery.

FUNGISTOP TOPICAL contains cetostearyl alcohol

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3. How to use FUNGISTOP TOPICAL

Do not share medicines prescribed for you with any other person.
Always use FUNGISTOP TOPICAL exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

FUNGISTOP TOPICAL should be applied thinly to the affected areas 2 - 3 times a day and rubbed in. A small amount of cream is usually sufficient for an area about the size of a palm. Successful treatment demands that FUNGISTOP TOPICAL be applied correctly and over a sufficiently long period of time. The normal period of treatment is 3 - 4 weeks.
For the relief of irritation of the vulva (external thrush) or the end of the penis which may be associated with thrush, the period of treatment is 1 - 2 weeks.
Topical treatment of fungal infections should be continued for approximately 2 weeks after the disappearance of all symptoms despite a rapid, subjective improvement, in order to prevent relapse.
For the treatment of athlete's foot and other fungal infections in skin folds, it is important to dry the area carefully.
FUNGISTOP TOPICAL cream is odourless, can be washed off and does not stain.

If you forget to apply dose of FUNGISTOP TOPICAL

Apply FUNGISTOP TOPICAL as soon as you remember and then continue applying the cream as usual.

4. Possible side effects

FUNGISTOP TOPICAL can have side effects.
Not all side effects reported for FUNGISTOP TOPICAL are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using FUNGISTOP TOPICAL, please consult your healthcare provider for advice.

If any of the following happens, stop using FUNGISTOP TOPICAL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat,
- swallowing or breathing problems,
- hives, rash or itching,
- abnormally low blood pressure, which includes symptoms like dizziness, light-headedness, feeling sick, or fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to FUNGISTOP TOPICAL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequency unknown

- itching,
- rash,
- blisters,
- burning,
- discomfort,
- swelling,
- irritation,
- pins and needles,
- redness or peeling of skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of FUNGISTOP TOPICAL.

5. How to store FUNGISTOP TOPICAL

- Store at or below 25 °C in a well closed container, protected from light.
- Store all medicines out of reach of children.
- Do not use after expiry date printed on the tube or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FUNGISTOP TOPICAL contains

The active substance is clotrimazole.
The other ingredients are propylene glycol, purified water, imidurea (preservative), Gujstat (mixture of parabens) 0,275 % *m/m*, liquid paraffin, Cremophor A25, Cremophor A6 and cetostearyl alcohol.

What FUNGISTOP TOPICAL looks like and contents of the pack

A soft smooth cream, free from gritty particles.
FUNGISTOP TOPICAL is packed into a 20 g printed aluminium tube in an outer carton.

Holder of certificate of registration and manufacturer

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Registration number

27/20.2.2/0337

FUNGISTOP TOPICAL

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:

S1

FUNGISTOP TOPICAL 1 % *m/m* room
Klotrimasool

Lees hierdie hele pamflet noukeurig deur omdat dit belangrike inligting vir jou bevat
- FUNGISTOP TOPICAL is beskikbaar sonder 'n dokter se voorskrif vir jou om 'n ligte siekte te behandel. Nietemin moet jy FUNGISTOP TOPICAL steeds versigtig gebruik om die beste resultate daaruit te kry.
- Bewaar hierdie inligtingspamflet. Jy sal dit dalk weer moet lees.
- Moenie FUNGISTOP TOPICAL met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies benodig.
- Jy moet 'n dokter raadpleeg indien jou simptome nie verbeter nie.

Wat is in hierdie pamflet

1. Wat FUNGISTOP TOPICAL is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy FUNGISTOP TOPICAL gebruik
3. Hoe om FUNGISTOP TOPICAL te gebruik
4. Moontlike newe-effekte
5. Hoe om FUNGISTOP TOPICAL te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat FUNGISTOP TOPICAL is en waarvoor dit gebruik word
Die aktiewe bestanddeel in FUNGISTOP TOPICAL is klotrimasool. Klotrimasool behoort aan 'n groep medisyne wat asole genoem word en is 'n teenswammedisyne wat die oorsaak van swamvelinfeksies beveg.
FUNGISTOP TOPICAL word gebruik vir die behandeling van swamvelinfeksies soos omlope, atleetvoet, pityriasis versicolor (wat kolle van verkleurde vel veroorsaak) en swaminfeksies van die weefsels langs die nael van 'n vinger of toon. Dit word ook gebruik om irritasie van die vulva (uitwendige sproei) of die einde van die penis te verlig, wat met sproei geassosieer kan word.

2. Wat jy moet weet voordat jy FUNGISTOP TOPICAL gebruik
Moenie FUNGISTOP TOPICAL gebruik nie:
Indien jy hipersensitief (allergies) is vir klotrimasool of enige van die ander bestanddele van FUNGISTOP TOPICAL (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met FUNGISTOP TOPICAL:
- Moenie rook of naby oop vlamme gaan nie - risiko van ernstige brandwonde. Materiale (klere, beddegoed, verbande ens) wat in kontak was met FUNGISTOP TOPICAL brand makliker en is 'n ernstige brandgevaar. Om klere en beddegoed te was kan die opbou van die produk verminder, maar dit nie heeltemal verwyder nie.
- FUNGISTOP TOPICAL kan die doeltreffendheid en veiligheid van lateks (rubber) produkte soos kondome en diafragmas (metode van voorbehoedmiddel) verminder. Indien jy FUNGISTOP TOPICAL room op die vulva of penis gebruik, moet jy alternatiewe voorsorgmaatreëls gebruik vir ten minste vyf dae nadat jy hierdie produk gebruik het.
- FUNGISTOP TOPICAL is slegs vir uitwendige gebruik en is nie bedoel vir oftalmiese gebruik nie.

Ander medisyne en FUNGISTOP TOPICAL
Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)

Swangerskap, borsvoeding en vrugbaarheid
Indien jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy FUNGISTOP TOPICAL room gebruik.
Veiligheid en doeltreffendheid van FUNGISTOP TOPICAL is nie tydens swangerskap en borsvoeding vasgestel nie.
Geen menslike studies op vrugbaarheid is uitgevoer nie.

Bestuur en gebruik van masjiene
FUNGISTOP TOPICAL het geen of onbeduidende invloed op jou vermoë om 'n voertuig te bestuur of masjinerie te gebruik nie.

FUNGISTOP TOPICAL bevat cetostearieI alkohol
CetostearieI alkohol kan plaaslike velreaksies veroorsaak (bv. kontakdermatitis)

3. Hoe om FUNGISTOP TOPICAL te gebruik
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Gebruik altyd FUNGISTOP TOPICAL presies soos beskryf in hierdie pamflet of soos jou dokter, apteker of verpleegster jou vertel het. Gaan praat met jou dokter, apteker of verpleegster as jy nie seker is nie.

FUNGISTOP TOPICAL moet 2 - 3 keer per dag dun op die aangetaste areas toegedien word en ingevryf word. 'n Klein hoeveelheid room is gewoonlik voldoende vir 'n area omtrent so groot soos 'n palm. Suksesvolle behandeling vereis dat FUNGISTOP TOPICAL korrek en oor 'n voldoende lang tydperk toegedien word. Die normale behandelingsperiode is 3 - 4 weke.
Vir die verligting van irritasie van die vulva (uitwendige sproei) of die einde van die penis wat met sproei geassosieer kan word, is die behandelingsperiode 1 - 2 weke.
Topikale behandeling van swaminfeksies moet voortgesit word vir ongeveer 2 weke na die verdwyning van alle simptome ten spyte van 'n vinnige, subjektiewe verbetering, om terugval te voorkom.
Vir die behandeling van atleetvoet en ander swaminfeksies in velvoue, is dit belangrik om die area versigtig te droog.
FUNGISTOP TOPICAL room is reukloos, kan afgewas word en vlek nie.

Indien jy vergeet om 'n dosis FUNGISTOP TOPICAL aan te wend
Wend FUNGISTOP TOPICAL aan sodra jy onthou en gaan dan voort om die room soos gewoonlik aan te wend.

4. Moontlike newe-effekte
FUNGISTOP TOPICAL kan newe-effekte hê.
Nie alle newe-effekte wat vir FUNGISTOP TOPICAL aangemeld is, is in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid versleg, of as jy enige nadelige effekte ervaar tydens die gebruik van FUNGISTOP TOPICAL, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om FUNGISTOP TOPICAL te gebruik en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel,
- sluk- of asemhalingsprobleme,
- korwe, veluitslag of jeuk,
- abnormale lae bloeddruk, wat simptome kan insluit soos duiseligheid, lighoofdigheid, siek gevoel (naarheid) of floute.

Hierdie is almal baie ernstige newe-effekte. Indien jy hulle het mag jy dalk 'n ernstige allergiese reaksie op FUNGISTOP TOPICAL gehad het. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Frekwensie onbekend
- jeuk,
- uitslag,
- blasies,
- brandende gevoel,
- ongemak,
- swelling,
- irritasie,
- 'naalde en spelde',
- rooiheid of afskilfering van die vel.

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

Aanmelding van newe-effekte
As jy newe-effekte kry, praat met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA aanmeld deur die vorm **"Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy meer inligting verskaf oor die veiligheid van FUNGISTOP TOPICAL.

5. Hoe om FUNGISTOP TOPICAL te bewaar
- Bewaar teen of benede 25 °C in 'n goed geslote houer, beskerm teen lig.
- Bewaar alle medisyne buite bereik van kinders.
- Moet nie gebruik na die vervaldatum wat op die buis of karton gedruk is nie.
- Gee alle ongebruikte medisyne terug aan jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting
Waat FUNGISTOP TOPICAL bevat
Die aktiewe stof is klotrimasool.
Die ander bestanddele is propileenglikol, gesuiwerde water, imidureum (preserveermiddel), Gujstat (mengsel van parabene) 0,275 % *m/m*, vloeibare paraffien, Cremophor A25, Cremophor A6 en cetostearieI alkohol.

Hoe FUNGISTOP VAGINAL lyk en die inhoud van die verpakking
'n Sagte gladde room, vry van growwe deeltjies.
FUNGISTOP TOPICAL word verpak in 'n 20 g gedrukte aluminium buis in 'n buitenste karton.

Houer van registrasiesertifikaat en vervaardiger
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Hierdie pamflet is laas hersien
29 September 2023

Registrasienommer
27/20.2.2/0337