Applicant:	Biotech Laboratories (Pty) Ltd	1.3.2.1 PIL
Products Names:	FUNGISTOP VAGINAL (27/20.2.2/0338 – registered)	
Dosage form:	Cream	
Strength:	Each gram contains 10 mg clotrimazole	

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

FUNGISTOP VAGINAL 1 % *m/m* cream

Clotrimazole

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

- FUNGISTOP VAGINAL is available without a doctor's prescription for you to treat a mild illness. Nevertheless, you still need to use FUNGISTOP VAGINAL carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share FUNGISTOP VAGINAL with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

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

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

The active substance in FUNGISTOP VAGINAL is clotrimazole. Clotrimazole belongs to a group of medicines called azoles and is an antifungal medicine which fights the cause of infections such as vaginal thrush.

FUNGISTOP VAGINAL is used for the relief of vaginal itching burning and discharge associated with vaginal yeast infections (vaginal thrush).

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

Do not use FUNGISTOP VAGINAL:

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

Warnings and precautions

Take special care with FUNGISTOP VAGINAL:

- If you have vaginal infection, itching, burning and sometimes a white discharge you should consult a doctor.
- If there is no improvement within 3 days or if symptoms persist for more than 7 days, you may have a condition that requires medical treatment, you should consult your doctor.
- If you are having your menstrual period. Do not use FUNGISTOP VAGINAL during your menstrual period.
- If you have a fever, lower abdominal pain, back pain, foul smelling vaginal discharge, nausea, vaginal bleeding, and/or associated shoulder pain, you should consult a doctor.
- If symptoms return within 2 months of using FUNGISTOP VAGINAL.
- You should not use tampons, intra-vaginal douches, spermicides or other vaginal preparations while using FUNGISTOP VAGINAL.

- Avoid vaginal intercourse as it may result in vaginal infection and while using FUNGISTOP VAGINAL your partner could become infected.
- FUNGISTOP VAGINAL may reduce the effectiveness and safety of latex (rubber) products such as condoms and diaphragms (method of contraceptive). You will need to take additional contraceptive measures while using FUNGISTOP VAGINAL.
- FUNGISTOP VAGINAL may reduce the effectiveness of condoms and diaphragms, it would be best if you avoid vaginal intercourse during treatment, to prevent the transmission of HIV and sexually transmitted diseases (STD's), until symptoms of the candidiasis infection have resolved.
- Avoid contact with eyes.

Children and adolescents

FUNGISTOP VAGINAL is intended for use by adults and children 12 years of age and older.

Other medicines and FUNGISTOP VAGINAL

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

You should inform your doctor or pharmacist if you are taking oral tacrolimus or sirolimus (used to prevent organ rejection after a transplant).

The use of FUNGISTOP VAGINAL with these medicines might lead to increased tacrolimus or sirolimus plasma levels.

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 health care provider for advice before using FUNGISTOP VAGINAL.

Safety and efficacy of FUNGISTOP VAGINAL have not been established in pregnancy. You should not use FUNGISTOP VAGINAL during pregnancy.

Breastfeeding should be discontinued during treatment with FUNGISTOP VAGINAL.

No human studies on fertility have been performed.

Driving and using machines

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

FUNGISTOP VAGINAL contains cetostearyl alcohol

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

3. How to use FUNGISTOP VAGINAL

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

Always use FUNGISTOP VAGINAL 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.

The usual dose is the content of one applicator every evening for six (6) successive days.

You should insert FUNGISTOP VAGINAL as deeply as possible into the vagina in the evening before going to bed (see instructions for use of the applicator below).

Insertion is best achieved when lying back with legs slightly drawn up.

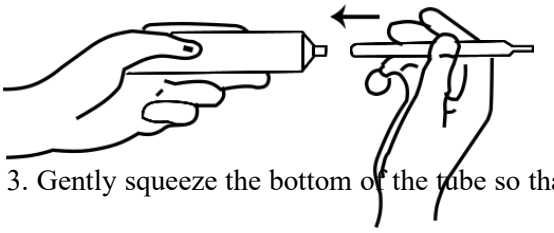
For thrush or inflammation of the outer vaginal area, the vaginal cream should be applied thinly to the external areas 2 – 3 times a day for 1 – 2 weeks.

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

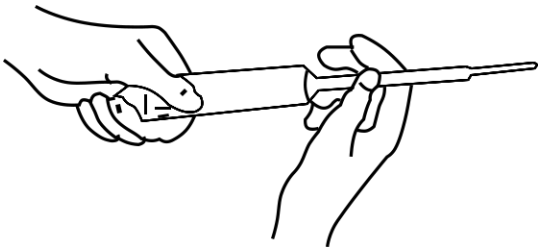
Directions for using the applicator:

1. Wash your hands thoroughly.

2. Screw the open end of one of the applicators over the opening of the tube of cream.



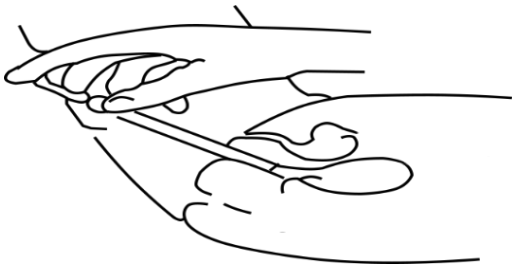
3. Gently squeeze the bottom of the tube so that the cream fills the applicator to the top, pushing the plunger out to almost its full extent.



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 your back with your legs pulled in a little towards your body.



6. Slowly push the plunger with your 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.

If you use more FUNGISTOP VAGINAL than you should

In case of unintended oral ingestion, stomach pain, loss of consciousness and shortness of breath may occur.

Treatment is symptomatic and supportive.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use a dose of FUNGISTOP VAGINAL

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

4. Possible side effects

FUNGISTOP VAGINAL can have side effects.

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

If any of the following happens, stop using FUNGISTOP VAGINAL 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, skin rash or itching,
- abnormally low blood pressure, which includes symptoms like dizziness, light-headedness, feeling sick (nausea), or fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- pelvic pain,
- vaginal bleeding.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency unknown

- stomach pain or lower abdominal cramps,
- nausea (feeling sick),
- increased need to pass urine,
- vaginal- or genital peeling (this is as a result of the exfoliation process of removing the damaged vaginal skin cells),
- itching, rash, redness, discomfort or burning,
- vaginal discharge,
- irritation,

- swelling,
- pain (e.g. vulvovaginal pain).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of FUNGISTOP VAGINAL.

5. How to store FUNGISTOP VAGINAL

- 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 VAGINAL contains

The active substance is clotrimazole.

The other ingredients are propylene glycol, purified water, imidurea (preservative), gujstat (preservative – *mixture of Parabens*), liquid paraffin, Cremophor A25, Cremophor A6 and cetostearyl alcohol.

What FUNGISTOP VAGINAL looks like and contents of the pack

A soft white cream.

FUNGISTOP VAGINAL is packed into a 30 g printed aluminium tube with 1 vaginal applicator and placed in an outer carton.

FUNGISTOP VAGINAL is packed into a 50 g printed aluminium tube with 6 or 8 vaginal applicators and placed in an outer carton.

Not all pack sizes may be marketed.

Holder of certificate of registration

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27/20.2.2/0338

Access to the corresponding Professional Information

The Professional Information Leaflet is available from Biotech Laboratories (Pty) Ltd. To request a digital copy, please email info@biotechlabs.co.za.