
This submission: Clinical Safety Update and PI/PIL reformat

Date of approval: 12 September 2021

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

FUNGISTOP TOPICAL

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 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.

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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 discoloured 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.

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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:

- 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 may be for external use only and is not intended for ophthalmic use.

Other medicines and FUNGISTOP TOPICAL

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

Pregnancy and breastfeeding

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 TOPICAL.

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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 or pharmacist has told you. Check with your doctor or pharmacist 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

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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 use a 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 health care 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, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

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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:

- itching,
- rash,
- blisters,
- burning,
- discomfort,
- swelling,
- irritation,
- 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 or pharmacist. You can also report side effects to SAHPRA via the “**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

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- 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), nipastat (preservative), liquid paraffin, Cremophor A25, Cremophor A6 and cetostearyl alcohol.

What FUNGISTOP TOPICAL looks like and contents of the pack

A soft white cream.

FUNGISTOP TOPICAL is packed into a 20 g printed aluminium tube in an outer carton.

Holder of certificate of registration and manufacturer

Biotech Laboratories (Pty) Ltd

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