# TRAVOGEN® CREAM

Isoconazole nitrate (10mg/g)

#### What is in this leaflet

- 1. What Travogen® Cream is used for
- 2. How Travogen® Cream works
- 3. Before you use Travogen® Cream
- 4. How to use Travogen® Cream
- 5. While you are using it
- 6. Side effects
- Storage and Disposal of Travogen®
   Cream
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

## What Travogen® Cream is used for

Travogen Cream is a medicine used to treat fungal infection of the skin, such as those between the toes, on the hands and in the genital region.

### How Travogen® Cream works

Travogen Cream contain isoconazole nitrate. It displays a very broad spectrum of antimicrobial action. Travogen Cream is effective against all major types of fungus and yeast that occur on human skin.

#### Before you use Travogen® Cream

- When you must not use it

Do not use Travogen Cream:

• if you are allergic to isoconazole nitrate or any of the other ingredients of this medicine (listed in section product description).

### - Before you start to use it

Pregnancy and breast-feeding

- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.
- Do not use Travogen Cream in the breast area if you are breastfeeding

## Taking other medicine

- Tell your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.
- There are no known interactions.

## How to use Travogen® Cream

- How much to use
  - Always use this medicine exactly your doctor or pharmacist has told

you as this may differ from the information in leaflet. Please consult a doctor or pharmacist if you do not understand the instructions on the medication label.

### - When to use it

 Apply Travogen Cream once daily to the infected parts of the skin

#### - How long to use it

- A general rule that applies to all fungal infections is that topical treatment must be performed over a period of 2-3 weeks, or even for 4 weeks in the case of persistent infection (especially when the spaces between the toes are infected). If prescribed specifically by the doctor, topical treatment may be used for longer periods of time.
- To avoid recurrence, the treatment should be continued for at least 2 weeks after the symptoms have resolved.
- Fungal infections are very persistent and prolonged. To ensure the success of treatment, you must use Travogen Cream as advised by your doctor or pharmacist and keep to the recommended measures of hygiene (see section Things you must do).
- You must talk to your doctor if you do not feel better or if you feel worse after 4 weeks.

#### - If you forget to use it

 Apply the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to apply the medicine and skip the missed dose. Do not apply double dose to make up for the missed dose.

## - <u>If you use too much (overdose)</u>

 Contact your doctor or nearest hospital emergency department if you, or someone else, has swallowed some cream. Do this even if there are no sign of discomfort or poisoning.

#### While you are using it

#### - Things you must do

- Use medicine as per instructed by doctor.
- Inform all doctors, dentists, and pharmacist that you are using Travogen Cream before any treatment.
- Tell your doctor immediately if you are pregnant while using this medicine.
- In case of persistent infection in the spaces between the toes, it is advisable to place a strip of gauze soaked with Travogen Cream between the toes.
- Careful personal hygiene will support the success of treatment. Affected skin areas, especially the spaces between the toes, must be carefully dried after washing and stockings or socks must be changed daily. You should air your shoes well when you take them off.
- To avoid recurrence, personal linen (face cloths, towels, underwear preferably cotton) should be changed daily and boiled.

### - <u>Things you must not do</u>

- Do not stop using Travogen Cream unless instructed by your doctor.
- Do not start using new medicine without consult your doctor or pharmacist.
- Do not give Travogen Cream to anyone, even if they have same symptoms or condition as you.
- You should not allow Travogen Cream to come into contact with the eyes when applying it to on the face.

#### - Things to be careful of

When Travogen Cream is used in the genital region, some of the ingredients may damage latex products, such as condoms and diaphragms, if they are used at the same time, thereby making them less effective. Use of latex products should be separated from Travogen Cream application by at least one hour.

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Driving and using machines

 No influence on the ability to drive and use machines has been observed during treatment with Travogen Cream.

#### Side effects

Like all medicines, Travogen Cream can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 patients treated):

 Skin irritation and burning sensation at the application site

*Uncommon* (may affect up to 1 in 100 patients treated):

- Itching or dryness at the application site
- Weeping skin rash
- Blisters
- Skin inflammation

*Rare* (may affect up to 1 in 1,000 patients treated):

- Swelling at the application site
- Skin fissures (cracks)

*Not Known* (frequency cannot be estimated from the available data):

- Redness or blisters at the application site.
- · Allergic skin reactions

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website <a href="mailto:npra.gov.my">npra.gov.my</a> [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

By reporting side affects you can help provide more information on the safety of this medicine.

# Storage and Disposal of Travogen® Cream

- <u>Storage</u> Store below 30°C.

Use within 3 months after opening.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or if the tube is leaking or if the tube nozzle cover is broken. The expiry date refers to the last day of that month.

#### - <u>Disposal</u>

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **Product Description**

#### - What it looks like

Travogen Cream is a white to slightly yellowish opaque cream.

#### - Ingredients

Active ingredient:

The active substance is: isoconazole nitrate (1% w/w). 1 g cream contains 10 mg isoconazole nitrate.

## Inactive ingredient:

White soft paraffin, liquid paraffin, cetyl stearyl alcohol, polysorbate 60, sorbitan monostearate, purified water.

#### - MAL number(s):

Travogen® Cream: MAL20001034AZ

## Manufacturer

LEO Pharma Manufacturing Italy S.r.l. Via E. Schering 21

20054 Segrate (Milan) Italy

## **Product Registration Holder**

DKSH Malaysia Sdn Bhd, B-11-01, The Ascent, Paradigm No.1, Jalan SS7/26A, Kelana Jaya 47301 Petaling Jaya Selangor Darul Ehsan

# **Date of revision**

18/03/2021

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