PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

Canesten® Topical Cream 10 mg/g

Clotrimazole

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

Canesten® Topical Cream is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Canesten® Topical Cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Canesten® Topical Cream 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 seven days.

What is in this leaflet

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

1. What Canesten® Topical Cream is and what it is used for

Canesten is used for all fungal infections of the skin caused by moulds, yeasts and fungi and also for skin diseases with secondary infections of these fungi.
These fungal infections may include among others:

1. Fungal infections of the skin and skin folds, (e.g. fungal infections of the groin, perineum, arm pits, Dhobies' or jock itch and barber's itch.)
2. Ringworm.
3. Fungal infections inbetween toes or fingers e.g. athlete's foot.
4. Candida vulvitis (vulval thrush).
5. Candida balanitis, (thrush of the glans penis).
6. Pityriasis (Tinea) versicolor.

7. Erythrasma.
8. Paronychias, associated with nail mycoses, (fungal infections of the tissues adjacent to the nail of a finger or toe).

2. What you need to know before you use Canesten® Topical Cream

Do not use Canesten® Topical:

- if you are hypersensitive (allergic) to clotrimazole or any of the other ingredients of Canesten® Topical Cream (listed in section 6).

Warnings and precautions

Special care should be taken with Canesten® Topical Cream:

- Direct contact with Canesten® Topical Cream may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.

- For external use only.

- Keep this medicine away from the eyes.

Other medicines and Canesten® Topical Cream

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

Canesten® Topical Cream with food and drink

The effect of Canesten® Topical Cream is not dependent on food and drink.

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 this medicine.

Driving and using machines

Canesten® Topical Cream has no or negligible influence on the ability to drive or use machinery.

Canesten® Topical Cream contains cetostearyl alcohol

Canesten® Topical Cream should not be used by persons allergic to cetostearyl alcohol.

3. How to use Canesten® Topical Cream

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

Always use Canesten® Topical Cream exactly as described in this leaflet or as your doctor or pharmacist or nurse told you. Check with your doctor or pharmacist or nurse if you are not sure.

Canesten® Topical Cream should be applied thinly to the affected areas two to three times a day and rubbed in.

Successful treatment demands that Canesten Topical Cream be applied correctly and over a sufficiently long period of time. The duration of treatment is generally three to four weeks.

TREATMENT OF FUNGAL INFECTIONS OF THE SKIN SHOULD BE CONTINUED FOR APPROXIMATELY 2 WEEKS AFTER THE DISAPPEARANCE OF 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.

Do not place an occlusive dressing (airtight covering such as kitchen plastic wrap) over the medicine.

If you use more Canesten® Topical Cream than you should

Wash the affected area immediately with water. Then, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use Canesten® Topical Cream

Do not apply double, or extra, dose to make up for forgotten individual doses.

4. Possible side effects

Canesten® Topical Cream can have side effects.

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

Tell your doctor if you notice any of the following:

- Skin rash, hives, blistering, burning, itching, peeling, redness, stinging, swelling, or other signs of skin irritation not present before the use of this medicine.

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 or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", foundonline 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 Canesten® Topical Cream .

5. How to store Canesten® Topical Cream

Store all medicines out of reach of children.

- Store at or below 30 °C
- Do not use after the expiry date stated on the carton and tube.

Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What Canesten® Topical Cream contains

- The active substance is clotrimazole
- The other ingredients are benzyl alcohol (as preservative) 2% m/m; octyldodecanol; cetyl esters wax; cetostearyl alcohol; sorbitan monostearate; polysorbate 60 and purified water.

What Canesten® Topical Cream looks like and contents of the pack

Canesten® Topical Cream is a soft, white cream.

Canesten® Topical Cream is packed in 15 g collapsible aluminium tube fitted with screw cap and placed in an outer carton.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

www.bayer.co.za

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