

## Proposed Clean Patient Information Leaflet

### SCHEDULING STATUS:

S1

### CANDASPOR® CREAM

Clotrimazole 10 mg

### Read all of this leaflet carefully before you start using CANDASPOR® CREAM

- Keep this leaflet. You may need to read it again.
- Do not share CANDASPOR® 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 7 days.

### What is in the leaflet

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

### 1.What CANDASPOR® CREAM is and what it is used for

The active substance in CANDASPOR® CREAM is clotrimazole. Antifungals for topical use – imidazole and triazole derivatives.

CANDASPOR® CREAM is used to treat 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, Dhobie itch or jock itch and barber's itch.)
2. Ringworm.
3. Fungal infections in-between 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 CANDASPOR® CREAM**

Do not use CANDASPOR® CREAM

If you are allergic to clotrimazole or any of the other ingredients in CANDASPOR® CREAM (listed in section 6).

## **Warnings and precautions**

### **Take special care with CANDASPOR® CREAM**

- Direct contact with CANDASPOR® CREAM may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.
- Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis)
- Not intended for ophthalmic use.

### **Other medicines and CANDASPOR® CREAM**

Always tell your health care 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 your baby, 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 taking this medicine.
- Safety and efficacy of CANDASPOR® CREAM has not been established in pregnancy.
- CANDASPOR® CREAM during pregnancy but only under the supervision of a physician or midwife.
- Breastfeeding should be discontinued during treatment with CANDASPOR® CREAM.

### **Driving and using machines**

CANDASPOR® CREAM has no or negligible influence on the ability to drive or use machinery.

### **3.How to use CANDASPOR® CREAM**

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

CANDASPOR® CREAM 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 CANDASPOR® CREAM be applied correctly and over a sufficiently long period of time. The normal period of treatment is 3-4 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.

**If you use more CANDASPOR® CREAM than you should**

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

In case of accidental ingestion, gastro-intestinal disturbances and central nervous system depression may occur. Treatment is symptomatic and supportive.

**If you forget to use CANDASPOR® CREAM**

Apply the cream as soon as possible and then continue the rest of your treatment as usual.

**4. Possible side effects**

CANDASPOR® CREAM can have side effects.

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

If any of the following happens, using CANDASPOR® CREAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rash.

- Swallowing or breathing problems.
- Swelling of your lips, face, throat or tongue.
- Weakness, feeling dizzy or faint.
- Nausea.

These are all very serious side effects. If you have them, you may have had a serious reaction to CANDASPOR® CREAM. 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:

Itching, rash, blisters, burning, discomfort, swelling, irritation, redness or peeling of skin.

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

**Tell your doctor if you notice any of the following:**

- Local reactions including skin irritation and burning may occur.
- Contact allergic dermatitis has been reported.
- In cases of systemic absorption, lower abdominal cramps, increase in urinary frequency or skin rash may occur.

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 “**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

CANDASPOR® CREAM

#### **5. How to store CANDASPOR® CREAM**

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light.
- Do not use after the expiry date on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewage systems (e.g. toilets).

#### **6. Contents Of The Pack And Other Information**

##### **What CANDASPOR® CREAM contains**

The active substance is clotrimazole.

Each 1 g of cream contains: 10 mg Clotrimazole

The other ingredients are:

Biopure 100, cetareth-25, cetareth-6 & stearyl alcohol, cetostearyl alcohol, liquid paraffin, nipastat, propylene glycol.

##### **What CANDASPOR® CREAM looks like and contents of the pack**

A soft, white cream.

Tube of 20g

**Applicant/PHCR:** Ranbaxy Pharmaceuticals (Pty) Ltd  
**Product proprietary name:** Candaspur Cream

**Dosage form and strength:** Cream/10 mg/1g  
**Date of amendment:** August 2021

### Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd  
14 Lautre Road,  
Stormill Ext 1  
Roodepoort, 1724  
South Africa

### This leaflet was last revised in

Will be allocated by SAHPRA upon approval of update.

### Registration Numbers

Y/20.2.2/290 (S.A)

**S2** BOT 0500760 (Botswana)

**NS1** 04/20.2.2/0999 (Namibia)

### Access to the corresponding Professional Information

To follow

#### References

1. Professional Information of **CANDASPOR® CREAM**, Ranbaxy Pharmaceuticals (Pty) Ltd, South Africa, August 2021.
2. Summary of Product Characteristics of Canesten, Bayer plc
3. SAHPRA guideline 2.14\_Guideline for Patient Information Leaflet for Human Medicines (Categories A and D)\_Jul19\_v2.

