

SCHEDULING STATUS:

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CANDASPOR® VAGINAL CREAM

Clotrimazole

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

- Keep this leaflet. You may need to read it again.
- Do not share CANDASPOR® VAGINAL 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® VAGINAL CREAM is and what it is used for.
2. What you need to know before you use CANDASPOR® VAGINAL CREAM.
3. How to use CANDASPOR® VAGINAL CREAM.
4. Possible side effects
5. How to store CANDASPOR® VAGINAL CREAM.
6. Contents of the pack and other information.

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

CANDASPOR® VAGINAL CREAM is used for the relief of vaginal itching, burning and discharge associated vaginal yeast (vaginal thrush).

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

2. What you need to know before you use CANDASPOR® VAGINAL CREAM

Do not use CANDASPOR® VAGINAL CREAM

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

If you are in your first three months of pregnancy.

If you are under 12 years of age.

If you are having your menstrual period.

Warnings and precautions

Take special care with CANDASPOR® VAGINAL CREAM

- 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 have abdominal pain, fever or a foul smelling vaginal discharge you should consult your doctor.
- If you are pregnant or think you may be pregnant or are nursing, do not use this medication except on the advice of a medical practitioner.
- If you experience symptoms within 2 months, consult a medical practitioner.
- If you are menstruating treatment should not be performed.
- You should not use tampons, intra-vaginal douches, spermicides or other vaginal preparations while using CANDASPOR® VAGINAL CREAM.
- Avoid vaginal intercourse as it may result in vaginal infection and while using CANDASPOR® VAGINAL CREAM your partner could become infected.

- CANDASPOR® VAGINAL CREAM is intended for use by adults and children 12 years of age and older only.
- **CANDASPOR® VAGINAL CREAM 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 CANDASPOR® VAGINAL CREAM.**
- As CANDASPOR® VAGINAL CREAM 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.

Other medicines and CANDASPOR® VAGINAL CREAM

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 tacrolimus or sirolimus (used to reduce the immune response to prevent rejection after an organ transplant).

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® VAGINAL CREAM has not been established in pregnancy.
- Breastfeeding should be discontinued during treatment with CANDASPOR® VAGINAL CREAM.
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Driving and using machines

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

CANDASPOR® VAGINAL CREAM contains cetostearyl alcohol which may cause local skin irritation (e.g. rash, itching or redness).

3.How to use CANDASPOR® VAGINAL CREAM

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

You should insert CANDASPOR® VAGINAL CREAM as deeply as possible into the vagina in the every night for six (or seven) days.

- Insertion is best achieved when lying back with legs pulled in a little towards the body.
- Two applications of 5 g vaginal cream can be used daily, i.e. one in the morning and one in the evening, for 6 days.
- The treatment should be continued if symptoms disappear and even during menstruation (i.e. complete for 6 days).

For the prevention of re-infection the partner should be treated locally with CANDASPOR® CREAM at the same time. This preparation does not stain the underwear.

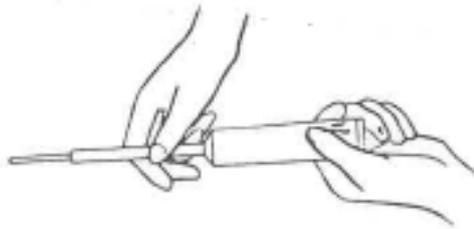
DIRECTIONS FOR USING THE APPLICATOR:

PREPARATION OF THE APPLICATOR:

1. Wash your hands thoroughly.
2. Ensure that the plunger is released and moves freely before attaching the applicator to the tube.
3. Screw the open end of one of the applicators over the opening of the tube of cream. The plunger of the applicator should be pushed right in at this stage.



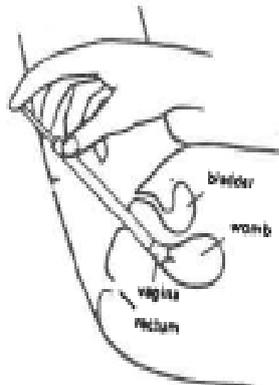
4. Gently squeeze the bottom of the tube so that the cream fills the applicator up to the point where the plunger reaches a stop.



5. Unscrew the tube of cream and replace it's cap.

INSERTING THE APPLICATOR:

6. 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 the back with the legs pulled in a little towards the body.

7. Slowly push the plunger with the forefinger until it stops.
8. Remove the applicator from the vagina and discard it.

EACH APPLICATOR IS FOR USE ONCE 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 2-3 times a day.

If you use more CANDASPOR® VAGINAL CREAM than you should

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

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

If you forget to use CANDASPOR® VAGINAL CREAM

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

4. Possible side effects

CANDASPOR® VAGINAL CREAM can have side effects.

Not all side effects reported for CANDASPOR® VAGINAL CREAM are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using CANDASPOR® VAGINAL CREAM, please consult your health care provider for advice.

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

- Hives or skin rash
- Temporary loss of consciousness – (this is as a result of an allergic reaction to the ingredients of CANDASPOR® VAGINAL CREAM)
- Itching
- Vaginal oedema (swelling)

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

Ranbaxy Pharmaceuticals (Pty) Ltd
Candaspor Vaginal Cream

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

- Pelvic pain
- Shortness of breath
- Vaginal bleeding

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

Tell your doctor if you notice any of the following:

- Abnormal low blood pressure – (symptoms are dizziness/light headedness, fainting, feeling sick)
- Genital peeling – (this is as a result of the exfoliation process of removing the damaged vaginal epithelium)
- Redness of the skin
- Discomfort
- Burning
- Irritation
- Abdominal 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 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® VAGINAL CREAM

4 How to store CANDASPOR® VAGINAL 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).

5 Contents Of The Pack And Other Information

What CANDASPOR® VAGINAL 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® VAGINAL CREAM looks like and contents of the pack

A soft, white cream.

Tube of 50g with 7 vaginal applicators.

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd

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Candaspor Vaginal Cream

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NS1 04/20.2.2/1000 (Namibia)