

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

CANDASPOR® VAGINAL CREAM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of cream contains:

Clotrimazole 10 mg

Preservatives: Nipastat 0,275 % *m/m*

Biopure 100 0,3 % *m/m*

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream

Soft white cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of vaginal itching, burning and discharge associated with recurrent vaginal yeast infections.

Vaginal Candidiasis.

4.2 Posology and method of administration

Fill enclosed vaginal applicator up to the point where the plunger reaches a stop (i.e. 5 g **CANDASPOR® VAGINAL CREAM**). Insert deeply into the vagina every night on retiring for six (or seven) consecutive days. This is best achieved when lying on the back with the legs pulled in a little towards the body. If individual cases should require it, 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 Candida vulvitis or vulvo-vaginitis the vaginal cream should be applied thinly to the external genitalia 2 or 3 times a day for 1 week.

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.

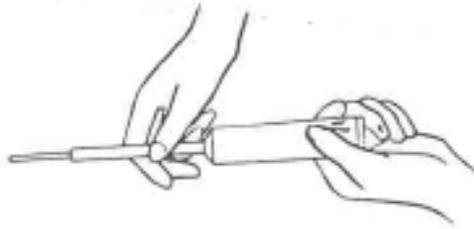
DIRECTIONS FOR USING THE APPLICATOR:

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.



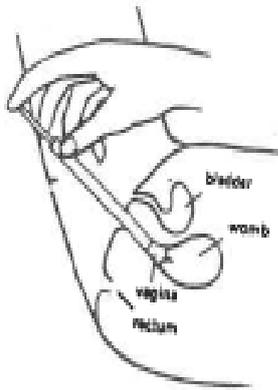
4. Gently squeeze the bottom of the tube so that the cream fills the applicator up to the point where the plunger reaches a stop.



5. Unscrew the tube of cream and replace its 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.

4.3 Contraindications

- Hypersensitivity to clotrimazole or to any of the excipients listed in section 6.1.
- The possibility of absorption of clotrimazole when administered vaginally cannot be excluded.

4.4 Special warnings and precautions for use

- Use only if you have already had a vaginal yeast infection diagnosed by a medical practitioner and you have the same symptoms now, otherwise consult your doctor. These symptoms include itching and burning of the vagina and sometimes a white discharge.
- If there is no improvement within 3 days or if symptoms have not disappeared within seven days, then consult a medical practitioner as not all vaginal infections are caused by yeasts.
- Consult a medical practitioner if you have abdominal pain, fever or a foul smelling vaginal discharge before or during use of this medication.
- 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.
- Recurrent infections may indicate an underlying medical cause. Patient should seek medical advice if symptoms return within 2 months.
- Treatment during the menstrual period should not be performed. The treatment should be completed before the onset of menstruation.
- Tampons, intravaginal douches, spermicides or other vaginal preparations should not be used while using **CANDASPOR® VAGINAL CREAM**.
- Avoidance of vaginal intercourse is recommended in case of vaginal infection and while using **CANDASPOR® VAGINAL CREAM**.
- **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 products such as condoms and diaphragms, when applied on the genital area (women: intravaginally, labia and adjacent area of the vulva; men: prepuce and glans of the penis). Additional contraceptive measures are required when using **CANDASPOR® VAGINAL CREAM**.

- As **CANDASPOR® VAGINAL CREAM** may reduce the effectiveness of condoms and diaphragms, patients should be advised to refrain from sexual intercourse to prevent transmission of HIV and sexually transmitted diseases (STD's) during treatment until the symptoms of candidiasis infection have resolved.
- Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis)

Special Precautions:

Contact with eyes should be avoided.

4.5 Interaction with other medicines and other forms of interaction

Concomitant medication with **CANDASPOR® VAGINAL CREAM** and oral tacrolimus (FK-506; immunosuppressant) may lead to increased tacrolimus plasma levels and similarly with sirolimus. Patients should thus be thoroughly monitored for symptoms of tacrolimus or sirolimus overdose, if necessary by determination of the respective plasma levels.

4.6 Fertility, pregnancy and lactation

Fertility

No human studies of the effects of clotrimazole on fertility have been performed, however, animal studies have not demonstrated any effects of the drug on fertility.

Pregnancy:

There is limited amount of data from the use of **CANDASPOR® VAGINAL CREAM** in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

Lactation:

Reported pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole and its metabolites in milk. Breastfeeding should be discontinued during treatment with

CANDASPOR® VAGINAL CREAM.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

System Class	Frequent	Less Frequent	Frequency Unknown
Immune system disorders			Allergic reaction (syncope, hypotension, dyspnoea, urticaria)
Gastrointestinal disorders			dominal pain Lower abdominal cramps
Skin and subcutaneous tissue disorders			skin rash allergic dermatitis irritation and burning
Renal and urinary disorders			increase in urinary frequency
Reproductive system and breast disorders			Genital peeling - (this is a result of the natural exfoliation process of removing damaged vaginal epithelium), pruritus, rash, oedema, erythema, discomfort, pelvic pain, vaginal haemorrhage.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions 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>

4.9 Overdose

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 20.2.2. Fungicides

Pharmacotherapeutic group: Gynaecological antiinfectives and antiseptics – imidazole derivatives

ATC Code: G01A F02

Mechanism of action

CANDASPOR® VAGINAL CREAM is a broad spectrum antimycotic with fungicidal properties.

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts and moulds.

5.2 Pharmacokinetic properties

A pharmacokinetic investigation after vaginal application reported that 3-10 % of clotrimazole is absorbed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Biopure 100

Cetareth-25

Cetareth-6 & stearyl alcohol

Cetostearyl alcohol

Liquid paraffin

Nipastat

Propylene glycol.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

Tube of 50 g with 7 vaginal applicators.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

Ranbaxy Pharmaceuticals (Pty) Ltd
Candaspur Vaginal Cream

7 HOLDER OF CERTIFICATE OF REGISTRATION

RANBAXY PHARMACEUTICALS (PTY) LTD

14 LAUTRE ROAD

STORMILL, EXT.1

ROODEPOORT

1724

SOUTH AFRICA

8 REGISTRATION NUMBER(S)

Y/20.2.2/289 (S.A)

S2 BOT 0500761 (Botswana)

NS1 04/20.2.2/1000 (Namibia)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

The date on the registration certificate of the medicine:

08 August 1991

10 DATE OF REVISION OF THE TEXT

13 January 2022