1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

CANDIZOLE V (cream)

COMPOSITION

Each 5 g of CANDIZOLE V vaginal cream contains 50 mg of clotrimazole.

Excipients:

Benzyl alcohol, cetostearyl alcohol, liquid paraffin, polysorbate, propylene glycol, purified water, sorbitan monostearate, white soft paraffin

Preservative:

Benzyl alcohol 1 % *m/m*

CATEGORY AND CLASS

A 20.2.2 Fungicides

PHARMACOLOGICAL ACTION

Clotrimazole has a fungicidal action on dermatophytes, yeasts, moulds and other fungi. It also acts on *Trichomonas vaginalis* and clotrimazole-sensitive bacteria.

INDICATIONS

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

CONTRAINDICATIONS

CANDIZOLE V is contraindicated in:

- Patients with a known sensitivity to clotrimazole.
- The possibility of absorption of clotrimazole when administered vaginally cannot be excluded.
- Safety in pregnancy has not been established.

WARNINGS AND SPECIAL PRECAUTIONS

Not for oral use.

i. 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.

ii. If there is no improvement in 3 days of if symptoms have not disappeared within seven days then consult a medical practitioner as not all vaginal infections are caused by yeasts.

iii. Consult a medical practitioner if you have abdominal pain, fever or foul-smelling vaginal discharge before or during use of this medication.

iv. If symptoms recur within 2 months consult a medical practitioner.

v. 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.

vi. Do not use in girls under 12 years of age, except on the advice of a medical practitioner.

vii. If skin rash or new irritation occurs, discontinue use.

INTERACTIONS

Not known.

HUMAN REPRODUCTION

Safety in pregnancy has not been established.

DOSAGE AND DIRECTIONS FOR USE

One 5 g application to be inserted per vagina at night on retiring for 6 (or 7) consecutive nights, even if symptoms disappear.

The enclosed vaginal applicator should be filled to the top with cream (i.e. 5 g CANDIZOLE V) and inserted deeply into the vagina.

It is best achieved when lying on the back with the legs pulled in a little towards the body.

The treatment should preferably be completed before menstruation begins. However, should menstruation commence before treatment is completed, the treatment should be continued during the menstrual period.

The vaginal cream should be applied thinly to the external genitalia 2 to 3 times daily for 1 to 2 weeks for *Candida* vulvitis.

As the partner may be the source of re-infection, he should concurrently use CANDIZOLE V locally.

Recurrence is common if the full course of treatment has not been completed.

SIDE EFFECTS

Local reactions including irritation and burning may occur in patients treated topically; contact allergic dermatitis has been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Symptoms

Gastrointestinal disturbance, urinary symptoms, elevation of liver enzymes, neutropenia and mental depression have been reported after administration of clotrimazole by mouth.

Treatment

Treatment is supportive and symptomatic.

IDENTIFICATION

A soft, smooth white cream.

PRESENTATION

50 g is packed in an aluminium tube sealed with a white high density polyethylene cone shaped cap. The tubes are placed in a unit cardboard carton with 6 high density polyethylene applicators and plungers together with a leaflet.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Store in airtight containers

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

27/20.2.2/0150

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

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Date of the most recent amendment to the professional information as approved by the Authority: 11 October 1993

Namibia: NS1 04/20.2.2/0009

DIRECTIONS FOR USING THE APPLICATOR

Preparing the applicator:

1. Wash hands thoroughly
2. Place the open end of one of the applicators over the opening of the tube cream. At this stage the plunger of the applicator should be pushed right in.

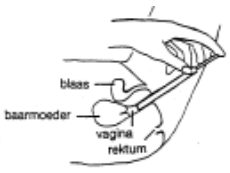


3. Squeeze the bottom of the tube gently so that the cream fills the applicator to the top, pushing the plunger out to its full extent.



4. Remove the tube of cream and replace the cap.

Inserting the applicator:



5. Insert the end of the applicator carefully as deeply as possible into the vagina. It is best achieved when lying on the back with the legs pulled in a little towards the body.
6. Slowly push the plunger with the forefinger until it stops.
7. Remove the applicator from the vagina and discard it.

USE EACH APPLICATOR ONCE ONLY

Use the surplus cream in the tube to treat any inflammation of the vulva (outer vaginal area) and nearby areas. Apply the cream thinly and rub in gently 2 to 3 times daily.

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