Applicant/PHCR:	Ascendis Pharma (Pty) Ltd	**Reg / Appl number**	28/20.2.2/0627
Product name:	Canex V	**Dosage form**	Cream
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1.3.1.1 Proposed package insert			

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

CANEX V Cream

COMPOSITION

Each 1 g of cream contains:

Clotrimazole	10 mg
Preservatives:	
Nipastat	0,275 % (m/m)
Imidurea	0,30 % (m/m)

CANEX V also contains the following inactive ingredients:

Propylene glycol, liquid paraffin, cremophor, cetostearyl alcohol and purified water.

PHARMACOLOGICAL CLASSIFICATION

A 20.2.2 Fungicides

PHARMACOLOGICAL ACTION

A broad spectrum antimycotic with fungicidal properties.

APPROVED 21/11 DATE 2019

INDICATIONS

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

CONTRAINDICATIONS

Possible sensitivity to clotrimazole.

The possibility of absorption of clotrimazole when administered vaginally cannot be excluded.

WARNINGS and SPECIAL PRECAUTIONS

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 or 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 a 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.

DOSAGE AND DIRECTIONS FOR USE

Fill enclosed vaginal applicator to the top (i.e. 5 g CANEX V cream). Insert deeply into the vagina every night on retiring for six (or 7) consecutive nights even during menstruation and even if symptoms disappear.

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 - 12 days.

For Candida vulvitis or vulvo-vaginitis the vaginal cream should be applied thinly to the external genitalia 2 - 3 times a day for 1 - 2 weeks.

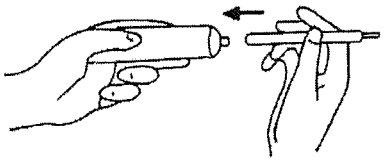
For the prevention of re-infection, the partner should be treated locally with CANEX V cream at the same time. This preparation does not stain the underwear.

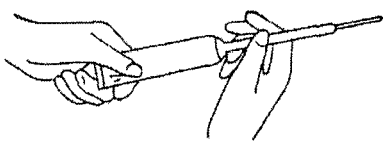
Wash applicator thoroughly with luke warm water. Store in a clean dry place.

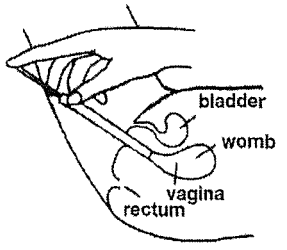
DITRECTIONS FOR USING THE APPLICATOR

Preparation of the applicator:

1. Wash your hands thoroughly.
2. Screw the open end of the applicator over the opening of the tube of cream. The plunger of the applicator should be pushed right in at this stage.
3. Gently squeeze the bottom of the tube so that the cream fills the applicator to the top pushing the plunger out to almost its full extent.
4. Unscrew the tube of cream and replace its cap.







Inserting the applicator:

5. Carefully insert the end of the applicator as deeply as possible into the vagina (making sure plunger does not fall out). This 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.
8. Wash applicator thoroughly with luke warm water and store in a clean, dry place.

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.

SIDE EFFECTS

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

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

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

IDENTIFICATION

A soft white cream.

PRESENTATION

Tubes of 50 g with 1 vaginal applicator.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER

28/20.2.2/0627

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

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Gauteng

DATE OF PUBLICATION OF THE PACKAGE INSERT

15 March 1996

Date of the most recently revised package insert as approved by Council

2 February 2015