PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

CANESTEN SOFT GEL OVULES 500 mg

Clotrimazole

Read all of this leaflet carefully because it contains important information for you.

- **CANESTEN SOFT GEL OVULES** is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **CANESTEN SOFT GEL OVULES** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **CANESTEN SOFT GEL OVULES** with any other person
- Ask your healthcare provider or pharmacist if you need more information or advice
- You must see a doctor if your symptoms worsen or do not improve after seven days

What is in this leaflet.

1. What CANESTEN SOFT GEL OVULES is and what it is used for

2. What you need to know before you use CANESTEN SOFT GEL OVULES.

3. How to use CANESTEN SOFT GEL OVULES.

4. Possible side effects

5. How to store CANESTEN SOFT GEL OVULES.

6. Contents of the pack and other information.

1. What CANESTEN SOFT GEL OVULES is and what it is used for.

Clotrimazole is an anti-fungal agent

CANESTEN SOFT GEL OVULES are used for the treatment of vaginal yeast infections which cause vaginal itching, burning, and discharge.

2. What you need to know before you use CANESTEN SOFT GEL OVULES.

Do not use CANESTEN SOFT GEL OVULES:

- If You are allergic to clotrimazole or any of the ingredients of **CANESTEN SOFT GEL OVULES** (listed in section 6)

Warnings and precautions

Take special care/ special care should be taken with **CANESTEN SOFT GEL OVULES**:

- **CANESTEN SOFT GEL OVULES** are not for oral use
- Do not use tampons, intravaginal douches, spermicides or other vaginal products while using **CANESTEN SOFT GEL OVULES**
- Avoid vaginal intercourse while using **CANESTEN SOFT GEL OVULES** because the partner could become infected.
- Seek medical advice if any of the following are applicable:
  - More than two infections of candida vaginitis in the last 6 months
  - Previous history of sexually transmitted disease or exposure to partner with sexually transmitted disease
  - Pregnancy or suspected pregnancy
  - Aged under 16 or over 60 years
  - Known sensitivity to imidazoles or other vaginal antifungal products
- Do not use Canesten Soft Gel Ovules if you have any of the following symptoms:
  - Irregular vaginal bleeding
  - Abnormal vaginal bleeding or a blood-stained discharge
  - Vaginal ulcers, blisters or sores
  - Lower abdominal pain or difficult urination
  - Redness, irritation or swelling associated with the treatment
  - Fever or chills

  - Nausea or vomiting
  - Diarrhea
  - Foul smelling vaginal discharge
- If there is no improvement in 3 days or if symptoms have not disappeared in 7 days, then consult a medical practitioner as not all vaginal infections are caused by yeasts.

Children and adolescents:

- Do not use **CANESTEN SOFT GEL OVULES** on girls who are under 16 years

Other medicines and CANESTEN SOFT GEL OVULES:

- Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines.)
- Canesten Soft Gel Ovules may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.

Pregnancy and breastfeeding:

- If you are pregnant or breastfeeding, 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 using **CANESTEN SOFT GEL OVULES**.
- **CANESTEN SOFT GEL OVULES** should not be used in the first 3 months of pregnancy except on the advice of a healthcare professional.
- During pregnancy the CANESTEN SOFT GEL OVULES should be inserted without using an applicator

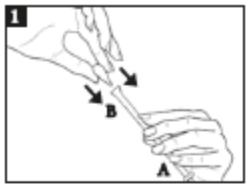
Driving and using machines:

- **CANESTEN SOFT GEL OVULES** has no or negligible influence on the ability to drive or use machinery.

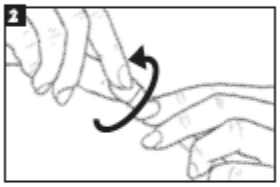
3. How to use CANESTEN SOFT GEL OVULES

- Always use **CANESTEN SOFT GEL OVULES** exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- One **CANESTEN SOFT GEL OVULE** should be inserted at night into the vagina as high as possible, using the applicator provided. This is best achieved when lying back with legs bent up.

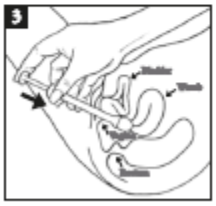
1. Remove the applicator from the packaging. Pull out the plunger A until it stops. Remove the pessary from the foil blister pack and place firmly into the applicator B.



2. Fix the Soft Gel Pessary firmly into the designated holder of the applicator B, by a light twist. The pessary fits tightly into the applicator.



3. Carefully put the applicator as deep as is comfortable into the vagina (this is easiest when lying on your back with your knees bent up). Holding the applicator in place, slowly press the plunger until it stops so that the pessary is deposited into the vagina.



4. Remove the applicator. Dispose of the applicator in a safe place, out of the reach of children. The applicator cannot be flushed down the toilet.

Since the pessary dissolves in the vagina, it may be helpful to wear a panty liner.

- A single dose treatment will be sufficient for the treatment of fungal infection; however, a second treatment may be carried out if necessary
- It is recommended that the treatment should be timed so as to avoid the menstrual period due to the risk of the ovule being washed out by menstrual flow.
- Not for use in children under 16 years.

If you use more CANESTEN SOFT GEL OVULES than you should:

- In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

4. Possible side effects

CANESTEN SOFT GEL OVULES can have side effects.

Not all side effects reported for CANESTEN SOFT GEL OVULES are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using **CANESTEN SOFT GEL OVULES,** please consult your health care provider for advice.

The following side effects have been reported and the frequency is unknown, you may need urgent medical attention. Tell your doctor if you notice any of the following:

- Allergic reactions (Fainting, Low blood pressure, Difficult breathing, Hives, Itching, Impaired consciousness).
- Abdominal pain/cramps
- Nausea
- Diarrhea
- Rash
- Increase in urinary frequency
- Swelling in the genitals
- Irritation
- Burning
- Genital peeling
- Pain in the pelvic area

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 **CANESTEN SOFT GEL OVULES**.

5. How to store CANESTEN SOFT GEL OVULES.

- Store all medicines out of reach of children.
- Store at or below 25 °C
- Store in the original carton in a dry place in order to protect from moisture
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

6. Contents of the pack and other information

What CANESTEN SOFT GEL OVULES contains:

- The active substance is Clotrimazole 500 mg
- The other ingredients are gelatine, glycerol, lecithin, Liquid paraffin, medium chain triglycerides, sunset yellow, titanium dioxide, quinolone yellow and white soft paraffin.

What CANESTEN SOFT GEL OVULES look like and contents of the pack.

- Soft Gel Ovules are teardrop soft gelatin capsule with a yellow opaque shell
- Each soft gel Ovule is packed into a blister consisting of formed clear PVC/PVdC/PVC laminate film with aluminum lidding foil.

The blister packaged in a folding carton with a leaflet and a disposable applicator.

Holder of Certificate of Registration

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Access to the corresponding professional information

The corresponding professional information can be accessed on the Bayer website: http://www.bayer.co.za