BIODEAL LABORATORIES LIMITED
NAIROBI, KENYA

ANNEX VI (b): PATIENT INFORMATION LEAFLET

QUERY RESPONSES ON REGISTRATION OF CANAZOL TABLETS- RWANDA FDA

PATIENT INFORMATION LEAFLET:
CANAZOL PESSARIES:
(CLOTRIMAZOLE)

- Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read itagain.
- If you have any further questions, please ask your doctor or pharmacist.

Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Canazol is and what it is used for
2. Before you use Canazol.
3. How to use Canazol.
4. Possible side effects
5. How to store Canazol.
6. Further information
7. Presentation

1. WHAT IS CANAZOLAND WHAT IS IT USED FOR?

The name of the medicine is Canazol. The active ingredient is Clotrimazole.

Canazol Pessary is recommended for the treatment of candidal vaginitis.

2. BEFORE YOU USE CANAZOL:

Do not use Canazol without medical advice:

- If you have had an allergy to any of the ingredients in the past
- If you think you may be pregnant
- In children under 3 years of age without medical advice.

3. HOW TO USE CANAZOL:

Canazol is for **'EXTERNAL USE ONLY**.

Adults: 200mg pessary should be inserted at night into the applicator provided, the pessary should be inserted as high as possible into the vagina.This is best achieved when lying back with legs bent up. A second treatment may be carried out if necessary.

Canazol pessaries need moisture in the vagina in order to dissolve completely, otherwise undissolved pieces of the pessary might crumble out of the vagina. Pieces of undissolved pessary may be noticed by women who experience vaginal dryness. To help prevent this it is important that the pessary is inserted as high as possible into the vagina at bedtime.

Generally: treatment during the menstrual period should not be performed due to the risk of the pessary being washed out by the menstrual flow. The treatment should be finished before the onset of menstruation.

Do not use tampons, intravaginal douches, spermicides or other vaginal products while using this product.

Vaginal intercourse should be avoided in case of vaginal infection and while using this product because the partner could become infected.

Children: As the product is used with an applicator, paediatric usage is not recommended.

If the condition does not improve consult your doctor.

NB: The pessary should be inserted into the vagina, as high as possible, using the applicator provided.

Wash your hands before removing the foil from the blister pack and again afterwards when you have used the applicator.

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



2.To fit the pessary into the applicator, the holder of the applicator needs to be squeezed lightly at both sides. The pessary fits tightly into the applicator and needs to be squeezed into the holder to about 1cm.



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. POSSIBLE SIDEEFFECTS:

If you find that your condition gets worse during treatment, you may be allergic to the preparation or have a skin infection.

Foul-smelling discharge. Irritation and damage inside the vagina.

Bleeding. Passing a small amount of urine during exercise or when you sneeze and cough.

Difficulty having sexual intercourse.

Urinary tract infections.

If this happens stop using the preparation and contact your doctor or pharmacist as soon as possible.

5. HOW TO STORE CANAZOL:

Do not use Canazol after the expiry date stamped on the tube and the pack. The expiry date refers to the last day of the month.

Canazol should be stored in a cool, dry place (below 30°C).

Keep this medicine out of the sight and reach of children Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how t dispose off medicines no longer required. These measures will help protect the environment.

6. FURTHERINFORMATION:

What Canazol contains

The active substance in Canazol is: Clotrimazole100mg tablets and Clotrimazole 200mg.

Further information on summary of product characteristics can be obtained from the regulatory department of Biodeal Laboratories Ltd. regulatoryaffairs@biodealkenya.com.

This product should only be used on the advice and prescription of a doctor.

7.PRESENTATION:

Canazol is available as100mg in packs of 6's and 200mg in packs of 3's packed in unit cartons with an applicator.

Biodeal

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