

MODULE -1
ADMINISTRATIVE INFORMATION FOR
CANDIFEM VAGINAL CREAM

1.5.3 PATIENT INFORMATION LEAFLET

Read this entire leaflet carefully before you starts taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

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1. Indication

- Candifem Vaginal cream is indicated for mixed infections of the genital region in
- Vaginal Candidiasis
 - Vaginal Trichomoniasis
 - Bacterial Vaginosis

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2. Pharmacokinetics

- Miconazole and Ornidazole readily penetrates the vaginal mucosa. Absorption of Miconazole is no more than 1.3% from the vagina.
- In the plasma the concentration of Ornidazole is low, only about 20% of the concentration after oral administration.
- Therefore, in case of pregnancy, vaginal application should be preferred because of the low plasma concentration of the drug.

3. Dosage & Administration

- About 5 g of Candifem Vaginal cream to be introduced each nights for 6 consecutive days with an applicator.
- The vaginal cream should be inserted as deeply as possible into the vagina at night. Insertion is best achieved with the applicator, when lying back with the legs slightly drawn up.
- Treatment during menstrual period should only be performed, if the clinical symptoms are pronounced.
- In general treatment should be completed before the onset of menstruation.
- To avoid re-infection, it is advisable to treat the partner locally with Candimale cream.

4. Tolerance

Candifem Vaginal Cream is well tolerated by most patients. No systemic toxicity is seen after topical use.

5. Adverse Effects

- Adverse reactions are rare and mild in most cases.
- Most frequently reported were local irritation, pruritus and burning sensation, especially at the start of treatment. If the patient finds this irritation intolerable, the treatment should be discontinued.

6. Directions for use of applicator

1. First pull out plunger of applicator until stops.
2. Open tube. Attach the applicator to the tube and, holding them firmly together, fill the applicator by carefully squeezing tube.
3. Disconnect the applicator from the tube. Introduce applicator as deeply as possible into the vagina (this is best done with lying on the back) and empty its contents into the vagina by pushing the plunger.
4. After use, withdraw applicator, thereafter wash in warm soapy water and dry completely.

Note :- Pregnant women should strictly follow the instructions of their

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Gynaecologist.

7. Contra-indications

Candifem Vaginal cream is contraindicated in individuals with a known hypersensitivity to Miconazole or Ornidazole or another ingredient of the cream.

8. Special warnings and precautions for use

- If local sensitisation or an allergic reaction occur, treatment should be discontinued.
- Appropriate therapy is indicated when the sexual partner is also infected.
- Candifem Vaginal cream does not stain skin or clothes.
- The concurrent use of latex condoms or diaphragms with vaginal anti-infective preparations may decrease the effectiveness of latex contraceptive agents. Therefore Candifem Vaginal cream should not be used concurrently with a latex condom or latex diaphragm. This effect is temporary & occurs only during the treatment.

9. Pregnancy and lactation

Since intravaginal absorption is limited, Candifem is considered safe for use during 2 and 3 trimester of pregnancy.

10. Storage

Store below 30°C, at a dry place. Do not freeze.

Keep medicines out of reach of children.

Candifem Vaginal cream must not be used after the expiry date.

11. Presentation

Tube of 30 g, with an applicator.

12. Important

FOR VAGINAL USE ONLY. NOT FOR ORAL USE.