

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Candid V3 (Clotrimazole Vaginal Inserts USP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:

Clotrimazole USP.....200 mg

Methyl Paraben USP 0.8 mg

Propyl Paraben USP 0.2 mg

Please refer section 6.1 for detailed list of excipients.

3. PHARMACEUTICAL FORM

Vaginal Tablets

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Clotrimazole 200mg Vaginal Tablets are recommended for the treatment of candidal vaginitis.

4.2. Posology and method of administration

The tablets should be inserted into the vagina, as high as possible, using the applicator provided. This is best achieved when lying back with legs bent up.

Adults:

One vaginal tablet should be inserted daily (preferably at night) for three consecutive days. A second treatment may be carried out if necessary.

There is no separate dosage schedule for the elderly.

Clotrimazole 200mg Vaginal Tablets need moisture in the vagina in order to dissolve completely, otherwise undissolved pieces of the tablet might crumble out of the vagina. Pieces of undissolved tablet may be noticed by women who experience vaginal dryness. To help prevent this it is important that the tablet is inserted as high as possible in to the vagina at bedtime.

Generally: Treatment during the menstrual period should not be performed due to the risk of the tablet 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:

Not for use in children under 16.

4.3. Contraindications

Hypersensitivity to clotrimazole or any other ingredient in this medicine.

4.4. Special warnings and precautions for use

Medical advice should be sought, if this is the first time the patient has experienced symptoms of candidal vaginitis.

Before using Clotrimazole 200mg Vaginal Tablets, medical advice must be sought if any of the following are applicable:

- more than two infections of candidal vaginitis in the last six months.
- previous history of a sexually transmitted disease or exposure to partner with sexually transmitted disease.
- pregnancy or suspected pregnancy.
- aged under 16 or over 60 years.
- known hypersensitivity to imidazoles or other vaginal antifungal products.

Clotrimazole 200mg Vaginal Tablets should not be used if the patient has any of the following symptoms whereupon medical advice should be sought:

- irregular vaginal bleeding.
- abnormal vaginal bleeding or a blood-stained discharge.
- vulval or vaginal ulcers, blisters or sores.
- lower abdominal pain or dysuria.
- any adverse events such as redness, irritation or swelling associated with the treatment.

- fever or chills.
- nausea or vomiting.
- diarrhoea.
- foul smelling vaginal discharge.

Patients should be advised to consult their physician if the symptoms have not been relieved within one week of using Clotrimazole 200mg Vaginal Tablets. The tablets can be used again if the candidal infection returns after 7 days. However, if the candidal infection recurs more than twice within six months, patients should be advised to consult their physician.

4.5. Interaction with other medicinal products and other forms of interaction

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently, the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

Concomitant medication with vaginal clotrimazole and oral tacrolimus (FK-506; immunosuppressant) might lead to increased tacrolimus plasma levels and similarly with sirolimus. Patients should thus be closely monitored for signs and symptoms of tacrolimus or sirolimus overdose, if necessary by determination of the respective plasma levels.

4.6. Fertility, pregnancy and lactation

Fertility:

No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

Pregnancy:

There are limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses. At the low systemic exposures of clotrimazole following vaginal treatment, harmful effects with respect to reproductive toxicity are not predicted.

Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

During pregnancy the tablet should be inserted without using an applicator.

Lactation:

Available pharmacodynamic/toxicological data in animals have shown excretion of clotrimazole/metabolites in milk after intravenous administration. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

4.7. Effects on ability to drive and use machines

The medication has no or negligible influence on the ability to drive or use machinery.

4.8. Undesirable effects

As the listed undesirable effects are based on spontaneous reports, assigning accurate frequency of occurrence for each is not possible.

Immune system disorders: allergic reaction (syncope, hypotension, dyspnea, urticaria, pruritus).

Reproductive system and breast disorders: genital peeling, pruritus, rash, oedema, erythema, discomfort, burning, irritation, pelvic pain, vaginal haemorrhage.

Gastrointestinal disorders: abdominal pain.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9. Overdose

No risk of acute intoxication is seen as it is unlikely to occur following a single vaginal or dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.

However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Gynaecological anti-infectives and antiseptics – imidazole derivatives

ATC Code: G01A F02

Mechanism of Action

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane.

Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc.

Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. The mode of action of clotrimazole is fungistatic or fungicidal depending on the concentration of clotrimazole at the site of infection. In-vitro activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

5.2. Pharmacokinetic properties

Pharmacokinetic investigations after vaginal application have shown that only a small amount of clotrimazole (3 – 10% of the dose) is absorbed. Due to the rapid hepatic metabolism of absorbed clotrimazole into pharmacologically inactive metabolites the resulting peak plasma concentrations of clotrimazole after vaginal application of a 500mg dose were less than 10 ng/ml, reflecting that clotrimazole applied intravaginally does not lead to measurable systemic effects or side effects.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryotoxicity, reduced fetal weights and decreased pup survival.

In rats clotrimazole and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4 by 24 hrs.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Inactive materialare Lactose Monohydrate, Maize Starch, Methyl Paraben, Propyl Paraben, Sodium Starch Glycolate, Talc, Magnesium Stearate & Colloidal Silicon Dioxide

6.2. Incompatibilities

None

6.3. Shelf life

48 months

6.4. Special precautions for storage

Store below 30°C. Protect from moisture and light.

6.5. Nature and contents of container and special equipment for use, administration or implantation

A printed carton with leaflet, applicator packed in polypropylene bag and a printed aluminium strip containing 3 white biconvex, uncoated vaginal tablets with G logo on one side and V3 on other side.

6.6. Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Glenmark Pharmaceuticals Limited
B/2, Mahalaxmi Chambers,
22, Bhulabhai Desai road, Mumbai – 400 026

8. MARKETING AUTHORISATION NUMBER(S)

FDA/SD.203-04169

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22.11.2006

10. DATE OF REVISION OF THE TEXT

Jan 2019

Patient Information Leaflet
Clotrimazole 200mg Vaginal Tablets
(Candid V-3)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without prescription. However, you still need to use Candid V-3 Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve in 7 days.
- If you have any unusual effects after using this product, tell your doctor or pharmacist.

In this leaflet

1. What is Candid V-3 (Clotrimazole 200mg) Vaginal Tablet and what is it used for?
2. Before you use Candid V-3 Vaginal Tablets
3. How to use Candid V-3 Vaginal Tablets
4. Possible side effects
5. How to store Candid V-3 Vaginal Tablets
6. Further information

1. WHAT IS CANDID V-3 TABLET AND WHAT IS IT USED FOR?

Candid V-3 Vaginal Tablets is indicated for the treatment of vaginal thrush. It is inserted into the vagina for treatment at the site of infection.

Only use this product if you have been previously diagnosed by your doctor as having vaginal thrush.

The active substance in Candid V-3 Vaginal Tablets is clotrimazole. Clotrimazole belongs to a group of medicines called azoles and is an antifungal agent which fights the cause of infections such as vaginal thrush.

2. BEFORE YOU USE CANDID V-3 TABLET

Do not use Candid V-3 Tablet:

- If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients of Candid V-3 Vaginal Tablets.
- During your period as it may be less effective.

Before using Candid V-3 Vaginal Tablet, you should see your doctor if:

- You are unsure whether you have thrush or this is the first time you have had these symptoms.
- You have had more than two infections of thrush in the last six months.
- You or your partner have ever had a sexually transmitted disease.
- You are aged under 16 or over 60.
- You have ever had an allergic reaction to Candid V-3 Vaginal Tablet or any other vaginal antifungal products.
- You have any of the following symptoms:
 - ✓ Irregular vaginal bleeding.
 - ✓ Abnormal vaginal bleeding or a blood-stained discharge.
 - ✓ Ulcers, blisters or sores of the vagina or vulva.

- ✓ Lower abdominal pain.
- ✓ Pain or difficulty in passing urine.
- ✓ Fever or chills.
- ✓ Feeling sick or vomiting.
- ✓ Diarrhoea.
- ✓ A foul smelling discharge from the vagina.

This is because Candid V-3 Vaginal Tablets may not be the right treatment for you.

Special precautions:

As with other pessaries, this product may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms. Consequently, you should use alternative precautions for at least five days after using this product.

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

Avoid vaginal intercourse while you have thrush and during use of this product because your partner could become infected.

Using other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Inform your doctor if you are taking tacrolimus or sirolimus (used to reduce the immune response to prevent rejection after an organ transplant).

Pregnancy and breast-feeding:

If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Candid V-3 Vaginal Tablet. If you have informed your doctor or midwife already, follow his/her instructions carefully.

To treat internal thrush, your doctor may recommend that you use the vaginal tablet without the help of an applicator.

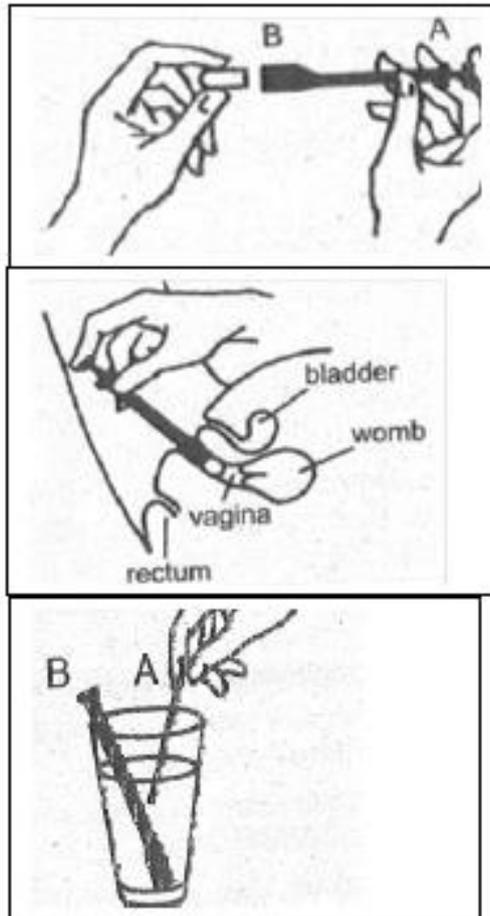
3. HOW TO USE CANDID V-3 Vaginal TABLET

If Candid V-3 Vaginal Tablet has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:

The applicator should be used to insert the vaginal tablet as high as possible into the vagina, preferably before going to sleep on **three consecutive nights** for convenient and comfortable treatment. Alternatively, two tablets may be inserted into the vagina before going to sleep on three consecutive nights.

SPECIAL DIRECTION FOR USING THE APPLICATOR:

1. Pull out plunger A until it stops. Place one vaginal Tablet into The applicator B.
2. Insert applicator containing the tablet carefully as deep as Possible into the vagina (this is done best by lying on the back).
3. Push plunger A until it stops, thereby depositing the tablet into the vagina. Withdraw the applicator.
4. After use, remove plunger A completely by pulling out of the Applicator B. Thereafter wash both in warm (not boiling) Soapy water, and dry completely.



Candid V-3 Vaginal Tablet is for use in the vagina only:

Do not put the tablet in your mouth or swallow it.

If the tablet is swallowed accidentally, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

If you forget to use Candid V-3 Vaginal Tablet:

Candid V-3 Vaginal Tablet should be used for six consecutive nights if one tablet is used, or three consecutive nights if two tablets are used. However, if you forget to insert a tablet, follow the advice given below:

When you remember, continue with your course of treatment. If you have forgotten for more than one day, your infection may not be fully treated, so if symptoms persist upon completion of this course, see your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Candid V-3 Vaginal Tablet can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the tablet. If you are allergic, a reaction will occur soon after you have used the medicine. If you experience an allergic reaction or the redness, burning, pain, itching or swelling get worse, stop using this product and tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital. Signs of an allergic reaction may include:

- Rash.

- Swallowing or breathing problems.
- Swelling of your lips, face, throat or tongue.
- Weakness, feeling dizzy or faint.
- Nausea.

After you use the tablet you might experience:

- Itching, rash, swelling, redness, discomfort, burning, irritation, vaginal peeling or bleeding.
- Pain in the abdomen or pelvic area.

If you experience any of the above effects or react badly to the tablet in any other way not listed in this leaflet, tell your doctor immediately.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE CANDID V-3 VAGINAL TABLETS

Store below 30°C. Protect from moisture and light.

6. FURTHER INFORMATION

What Candid V-3 Vaginal Tablet contains:

- The active substance is clotrimazole at strength of 200mg.
- The other ingredients are ...
- Lactose Monohydrate, Maize Starch, Methyl Paraben, Propyl Paraben, Sodium Starch Glycolate, Talc, Magnesium Stearate, Colloidal Silicon Dioxide

What Candid V-3 Vaginal Tablet looks like and contents of the pack:

A printed carton with leaflet, applicator packed in polypropylene bag and a printed aluminium strip containing 3 white biconvex, uncoated vaginal tablets with G logo on one side and V3 on other side.

7. Further information about vaginal thrush:

Vaginal thrush (candidiasis) is a common infection that most women suffer from at some time in their lives and is not caused by lack of personal hygiene.

Thrush is caused by a yeast (fungus) called Candida which lives harmlessly in the vagina and other parts of the body, without you even noticing it. However, the natural balance that keeps Candida under control can be upset by many factors such as hormonal changes (menstruation, contraceptive pill, pregnancy, menopause), poor health, antibiotics, perfumed soaps, bath additives and tight clothing.

If the natural pH balance is altered, the level of yeast increases and can develop into a thrush infection causing any of the following symptoms: persistent burning and/or itching around the vagina and vulva, redness, swelling and soreness of the tissues of the vagina and vulva and a whitish, odourless discharge from the vagina. Not everybody who has thrush has all these symptoms; you may have only one of them.

8. How to avoid future recurrences:

- Wear cotton knickers and loose clothing.
- Wash daily.
- After going to the toilet, wipe yourself from the front to back as a thrush infection may be transferred from the bowel.
- Change your sanitary protection regularly.
- Try to avoid wearing tights, nylon knickers and close fitting jeans.
- Try to avoid washing with perfumed soaps or using vaginal deodorants.
- Do not wash or rub yourself hard with sponges or flannels and avoid hot baths with strong perfumed oils.

If you are still worried or have any questions about the symptoms or the treatment of thrush, do not hesitate to ask your doctor or pharmacist for advice.

Marketing Authorisation Holder:

Glenmark Pharmaceuticals Limited, India

Manufacturer:

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