

SUMMARY OF PRODUCT CHARACTERIZATION

Candid V-1 Tablets

1. NAME OF THE MEDICINAL PRODUCT

Candid V-1 Vaginal Tablets (Clotrimazole Vaginal Inserts 500 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:

Clotrimazole USP 500 mg

Methyl Paraben USP/NF 0.8 mg

Propyl Paraben USP/NF 0.2 mg

refer section 6.1 for detailed list of inactive ingredients.

3. PHARMACEUTICAL FORM

Vaginal Tablets

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Candid V-1 Vaginal Tablets is 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.

Adults: One 500 mg Tablet should be inserted at night. Using the applicator provided, the Tablet 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 in the treatment of severe candidal vaginitis, non-albicans candidal vaginitis, candidal vaginitis in immunocompromised host and in the maintenance treatment of recurrent candidal vaginitis.

Candid V-1 Tablets need moisture in the vagina in order to dissolve completely; otherwise undissolved pieces of the Tablets might crumble out of the vagina. Pieces of undissolved Tablets may be noticed by women who experience vaginal dryness. To help prevent this it is important that the Tablets 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 Tablets 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.

For the prevention of reinfection, the partner should be treated locally with CANDID Cream if he is diagnosed with candidal balanitis.

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

4.3. Contraindications

Hypersensitivity to clotrimazole or any ingredient in this medicine

4.4. Special warnings and precautions for use

For vaginal use only

Not to be taken orally

Keep this and all drugs out of the reach of children

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

Before using Candid V-1 Tablets, medical advice must be sought if any of the following are applicable:

- more than two infections of candidal 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 hypersensitivity to imidazole's or other vaginal antifungal products.

Candid V-1 Tablets should not be used if the patient has any of the following symptoms where upon 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 Candid V-1 Vaginal Tablets. Candid V-1 Vaginal 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

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 (see section 5.3). 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 Tablets 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 (see section 5.3). 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.

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-infective 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 material are Lactose Monohydrate, Maize starch, Methyl Paraben, Propyl Paraben, Sodium Starch Glycolate, Talc, Magnesium Stearate, Colloidal Silicon Dioxide, Purified water.

6.2. Incompatibilities

Not applicable

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 containing a leaflet, an applicator packed in polypropylene bag and a printed aluminium strip.

6.6. Special precautions for disposal

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.203-04168

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22.11.2006

10. DATE OF REVISION OF THE TEXT

May 2017

Patient Information Leaflet

Candid V-1 (Clotrimazole 500 mg) Vaginal Tablets

Read all of this leaflet carefully before you start using 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. Do not give it to anyone else under any circumstances.
- If you have any unusual effects after using this product, tell your doctor.

In this leaflet

1. What is Candid V-1 (Clotrimazole 500mg) Vaginal Tablet and what is it used for?
2. Before you use Candid V-1 Vaginal Tablets
3. How to use Candid V-1 Vaginal Tablets
4. Possible side effects
5. How to store Candid V-1 Vaginal Tablets
6. Further information

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

Candid V-1 Vaginal Tablet is a full course of treatment for vaginal thrush (candidiasis). It is inserted into the vagina for treatment at the site of infection. The active substance in Candid V-1 Vaginal Tablet 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-1 TABLET/PESSARY

Do not use Candid V-1 Vaginal Tablet:

- If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients of Candid V-1 Tablets (*see Section 6. Further Information*).
- During your period as it may be less effective.

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-1 Vaginal Tablet. If you have informed your doctor or midwife already, follow his/her instructions carefully.

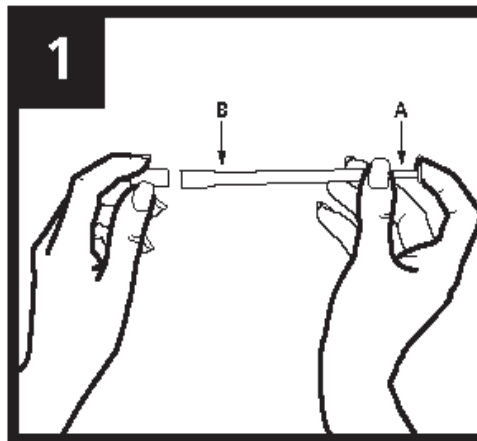
To treat internal thrush, your doctor may recommend that you use the pessary without the help of an applicator.

3. HOW TO USE CANDID V-1 TABLET/PESSARY

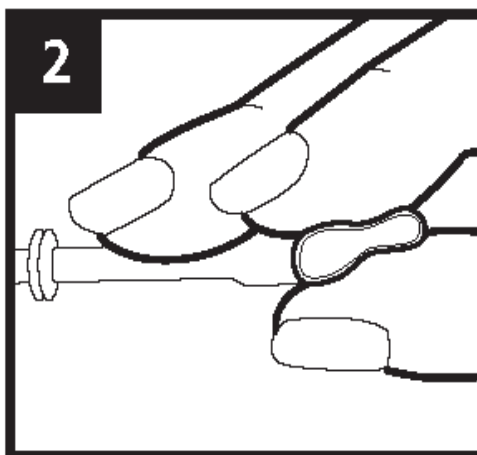
Unless directed otherwise by your doctor, the pessary should be inserted as high as possible into the vagina, preferably before going to sleep at night for convenient and comfortable treatment.

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

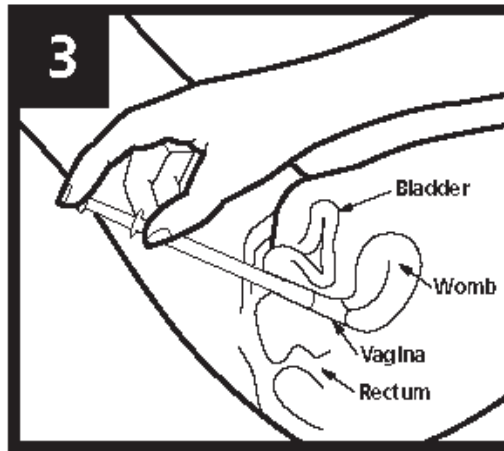
1. Remove the applicator from the packaging. Pull out the plunger A until it stops. Remove the pessary from the foil blister pack and place firmly into the applicator B.



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. 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 because it is quite common to notice a white chalky residue after using the pessary. This does not mean that the treatment has not worked. However, if you notice pieces of undissolved pessary, speak to your doctor or a pharmacist, as the treatment may not have worked properly.

The symptoms of thrush should disappear within three days of treatment. If no improvement is seen after seven days you must tell your doctor.

Candid V-1 Vaginal Tablet/Pessary is for use in the vagina only:

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Candid V-1 Vaginal Tablet/Pessary can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the pessary. 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 pessary 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 pessary in any other way not listed in this leaflet, tell your doctor immediately.

5. HOW TO STORE CANDID V-1 VAGINAL TABLETS/PESSARY

Keep out of the reach and sight of children.

Do not use Candid V-1 Vaginal Tablet/Pessary after the expiry date which is stated at one end of the carton and on the foil blister strip of the pessary. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Candid V-1 Vaginal Tablet/Pessary contains:

- The active substance is clotrimazole at strength of 500mg.
- Excipients: Lactose Monohydrate, Maize starch, , Sodium Starch Glycolate, Talc, Magnesium Stearate, Methyl Paraben, Propyl Paraben, Colloidal Silicon Dioxide, Purified water

What Candid V-1 Vaginal Tablet/Pessary looks like and contents of the pack:

Candid V-1 Vaginal Tablet/Pessary contains a white pessary held inside a foil blister and an applicator for insertion of the pessary into the vagina.

Marketing authorisation holder:

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

Manufacturer:

Glenmark Pharmaceuticals Limited
Plot No. E-37,39, D-Road, MIDC, Satpur,
Nashik – 422 007, Maharashtra State, India.

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.

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.

This leaflet was last revised in May 2017.