SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Candid V-3 Vaginal Tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:

Clotrimazole USP .....200 mg

Refer to section 6.1 for detailed list of excipients.

3. PHARMACEUTICAL FORM

Vaginal Tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Candid V-3 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 200 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-3 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 V3 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 V3 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 V3 Vaginal Tablets. Candid V3 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 overdosage, 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.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

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

Excipients: Lactose Monohydrate, Maize starch, Methyl Paraben, Propyl Paraben. Sodium Starch Glycolate, Talc, Magnesium Stearate and Colloidal Silicon Dioxide.

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 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)

H1990/5964/R1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18.04.1990

10. DATE OF REVISION OF THE TEXT

May 2017