1.5 PRODUCT INFORMATION

1.5.1 PRESCRIBING INFORMATION

(SUMMARY OF PRODUCT CHARACTERISTICS)

Enclosed

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1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT
C-ZOLE [Clotrimazole Vaginal tablets BP 100 mg]
Strength: 100 mg
Pharmaceutical Form: Vaginal tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each uncoated Vaginal tablet contains:
Clotrimazole B.P……100 mg
Excipients ……q.s.

3. PHARMACEUTICAL FORM

Uncoated tablet

White, bullet shaped, biconvex uncoated tablets having tapering embossed “VG” on one side of each tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

C-zole 100mg vaginal tablets are recommended for the treatment of candidal vaginitis.

4.2 Posology and method of administration

The vaginal tablet should be inserted into the vagina, as high as possible, using the applicator provided.
Adults: One 100mg vaginal tablet should be inserted at night. Using the applicator provided, the vaginal 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.
Generally:
Treatment during the menstrual period should not be performed due to the risk of the vaginal 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.
Children: Not for use in children under 16.

4.3 Contraindications

The first trimester of pregnancy.
Hypersensitivity to clotrimazole or any other ingredient in this medicine.

4.4 Special warnings and special precautions for use

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

Before using C-zole 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 imidazoles or other vaginal antifungal products.

C-zole 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 C-zole Vaginal tablet. C-zole Vaginal tablet 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 FPPs 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. Patients should thus be closely monitored for signs and symptoms of tacrolimus overdosage, if necessary by determination of the respective plasma levels.

4.6 Pregnancy and lactation

Data on a large number of exposed pregnancies indicate no adverse effects of Clotrimazole on pregnancy or on the health of the foetus/newborn child. To date, no relevant epidemiological data are available.

Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.
During pregnancy the Vaginal tablet should be inserted without using an applicator.

4.7 Effects on ability to drive and use machines

Not applicable.

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, discomfort, burning, and irritation, pelvic pain Gastrointestinal disorders: abdominal pain

4.9 Overdose

In the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). It should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: G01A F02
Clotrimazole is an imidazole derivative with a broad spectrum of antimycotic activity.

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

Pharmacodynamic Effects
Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc.
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 mcg/ml, reflecting that clotrimazole applied intravaginally does not lead to measurable systemic effects or side effects.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to the information included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Microcrystalline cellulose
Pregelatinised starch
Purified Water
Maize Starch
Tween 80(Sorbox 80)
Adipic acid
Sodium Bicarbonate
Colloidal Silicon Dioxide
Magnesium stearate
Stearic Acid

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 Months

6.4 Special precautions for storage
Do not store above 30°C. Store in dry place.

6.5 Nature and contents of container

Alu. Alu. Strip pack of six vaginal tablets.
Pack sizes: Strip of six tablets is packed in one printed carton with an applicator and pack insert.

6.6 Instructions for use and handling and disposal

1. Pull out plunger until it stops. Place the Vaginal tablet into the applicator.
2. Carefully insert the applicator containing the vaginal tablet as deeply as is comfortable into the vagina. This is best done with the patient lying on her back with the knees bent up.
3. Push plunger carefully until it stops, thereby depositing the vaginal tablet into the vagina. Withdraw the applicator and dispose of it hygienically.

7. MARKETING AUTHORISATION HOLDER

UMEDICA LABORATORIES PVT. LTD.
302, 3rd Floor, Dalamal House, Jamnalal Bajaj Road,
Nariman Point, Mumbai – 400021.
Tel No. (022)62455050/40028503
Email: regn_ho@umedicalabs.com

8. MARKETING AUTHORIZATION NUMBER

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9. DATE OF FIRST <REGISTRATION> / RENEWAL OF THE <REGISTRATION>

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10. DATE OF REVISION OF THE TEXT

20/04/2020