SUMMARY OF PRODUCT CHARACTERSTICS

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1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Product Name **: CLORIFORT (Clotrimazole Vaginal Tablets BP 100mg)**
Strength **:** 100 mg
Pharmaceutical Form **:** Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Label Claim:
Each uncoated vaginal tablet contains:
Clotrimazole BP….. 100mg
Excipients: q.s.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet
White, bullet shape, biconvex uncoated tablets having tapering, embossed "VG" on one side and plain on other side of each tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
Clorifort 100mg Pessaries are recommended for the treatment of candidal vaginitis.

4.2 Posology and method of administration
The pessaries 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:

Two pessaries should be inserted daily (preferably at night) for three consecutive days. Alternatively, one pessary may be inserted daily for six days, preferably at night. A second treatment may be carried out if necessary.

There is no separate dosage schedule for the elderly.

Clorifort pessaries need moisture in the vagina in order to dissolve completely, otherwise undissolved pieces of the pessary might crumble out of the vagina. Pieces of undissolved pessary may be noticed by women who experience vaginal dryness. To help prevent this it is important that the pessary 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 pessary 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 Clorifort 100mg Pessaries, 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.

Clorifort 100mg Pessaries 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 Clorifort 100mg Pessaries. The pessaries 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 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. 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 pessary 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

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.

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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 antiinfectives 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

Lactose Monohydrate
Microcrystalline Cellulose
Pregeletinised Starch
Starch (Maize)
Tween 80 (Sorbox 80)
Purified water
Adipic Acid
Sodium Bicarbonate
Colloidal Silicon Dixide
Magnesium Stearate
Stearic Acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store below 30° C.

6.5 Nature and contents of container

Blister pack of 6 Tablets

Pack sizes: Alu PVC blister of 6 Tablets. 1 such blisters are packed in one printed carton with pack insert & applicator.

6.6 Instructions for use and handling and disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER
UMEDICA LABORATORIES PVT. LTD.
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(Phone: +91 – 22 – 62455050, 40028503)
Email : exports@umedicalabs.com

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

Registration No 07764/09521/NMR/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/09/2022

10. DATE OF REVISION

July 2023