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CLOTHREE

VAGINAL TABLETS

Composition

Each vaginal contains:

Active Ingredient

Clotrimazole	200 mg

Other Ingredients

Lactose monohydrate, microcrystalline cellulose, crospovidone, calcium lactate pentahydrate, povidone, lactic acid, magnesium stearate, silicon dioxide.

Each vaginal tablet contains 612 mg lactose.

Mechanism of Action

Clotrimazole is an imidazole derivative with a broad-spectrum of any mycotic activity. Clotrimazole acts against fungi by inhibiting ergosterol synthesis. This inhibition leads to structural and functional impairment of the cytoplasmic membrane, altering its permeability. As a result, loss of essential intracellular elements may occur. Azoles also inhibit biosynthesis of triglycerides and phospholipids by fungi. In addition, azoles inhibit oxidative and peroxidative enzyme activity, resulting in intracellular buildup of toxic concentrations of hydrogen peroxide, which may contribute to deterioration of subcellular organelles and cellular necrosis. In candida albicans, azoles inhibit transformation of blastospores into invasive mycelical form.

Indications

Local treatment of vaginal infections due to Candida species (particularly *Candida albicans*), *trichomonas vaginalis*, as well as mycotic infections complicated by other micro-organisms sensitive to the drug.

Contraindications

Known hypersensitivity to clotrimazole or to any ingredient of the preparation.

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 this product, medical advice must be sought if any of the following situations exist:

- 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.

Clothree vaginal 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 (disgusting) smelling vaginal discharge.

Patients should be advised to consult their physician if the symptoms have not been relieved within 3 days.

This product may reduce the effectiveness and safety of latex products such as condoms and diaphragms. The effect is temporary and occurs only during treatment.

Use in Pregnancy

While controlled clinical studies in pregnant women do not exist, epidemiological investigations give no indication that harmful effects on the mother and child should be anticipated when clotrimazole is used during pregnancy. However, as with all drugs in the first 3 months of pregnancy, this product should only be used after first consulting a doctor.

Sanitation of the birth canal should be ensured particularly during the last 4-6 weeks of pregnancy.

Use during Lactation

It is not known whether this drug is excreted in human milk. Therefore, the risk-benefit must be considered when administering this drug to nursing mothers.

Use in Geriatrics

Appropriate studies on the relationship of age on the effects of vaginal azoles have not been performed in the geriatric population. However, no geriatrics-specific problems have been documented to date.

Adverse Reactions

Rarely patients may experience local mild burning or irritation immediately after inserting the pessary. Very rarely the patient may find this intolerable and stop treatment.

Other undesirable effects include:

*Body as a whol*e: allergic reactions (syncope, hypotension, dyspnea, gastrointestinal disorders, swelling of the lips, face or tongue, or hives), pain

Skin and appendages: pruritis, rash, redness, irritation, blistering, vaginal burning, itching, discharge, or other irritation not present before therapy .

Drug Interactions

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives (see Warnings). 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

Directions for Use

One vaginal tablet in the evening before bedtime, to be inserted as deep as possible into the vagina, for three consecutive nights. This is best achieved when lying back with the legs up.

Notes:

Treatment during the menstrual period should not be performed. The treatment should be finished before the onset of menstruation.

The sexual partner should also undergo local treatment if symptoms, e.g. pruritus, inflammation, etc. are present.

Overdosage

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). It should be carried out only if the airway can be protected adequately.

Registration Number: 127 41 30473 00

Storage

Store this medicine in a cool place. Do not freeze.

Presentation

Packs of 3 vaginal tablets with applicator.

Manufacturer

Teva Pharmaceutical Industries Ltd
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