

DAZOLE®
(CLOTRIMAZOLE USP).

Description.

Clotrimazole, an imidazole derivative with broad spectrum anti-fungal and Trichomonacide activity.

Composition

Each 5ml of Dazole mouth paint contains: Clotrimazole 1%w/v

Each pessary contains: Clotrimazole USP 100 mg.

Pharmacology.

Clotrimazole, an imidazole derivative with a broad spectrum of antimycotic activity. It interacts with yeast 14- α demethylase, a cytochrome P-450 enzyme that converts lanosterol to ergosterol, an essential component of the membrane. In this way, clotrimazole inhibits ergosterol synthesis, resulting in increased cellular permeability. Clotrimazole may also inhibit endogenous respiration, interact with membrane phospholipids, inhibit the transformation of yeasts to mycelial forms and the uptake of purine, impair triglyceride and/or phospholipid biosynthesis, and inhibit the movement of calcium and potassium ions across the cell membrane by blocking the ion transport, through the Gardos channel pathway.

Pharmacokinetics.

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 were less than 10 ng/ml, reflecting that clotrimazole applied intravaginally does not lead to measurable systemic effects or side effects.

Indications

Dazole mouth paint is primarily used to treat the oral fungal infection called oral candidiasis—which is caused by fungal organisms of the candida genus.

Dazole 100mg Pessaries are recommended for the treatment of candidal vaginitis.

Dosage.

10 to 20 drops ($\frac{1}{2}$ to 1 mL) of Dazole Mouth Paint are gently applied in the mouth, 3 to 4 times daily, preferably with the help of a cotton bud. Care should be taken to ensure that all the lesions in the mouth are covered. Attention should be directed to the control of any factor that may predispose the patient to infection as this will help prevent recurrence. Children should be supervised during the use of Dazole mouth paint. You should apply it over all the lesions in your mouth, and treatment should continue until all white patches in the mouth are eliminated.

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. Not for use in children under 16 years.

Contra-indications.

Hypersensitivity to Clotrimazole or any other ingredient in this medicine.

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.

- 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 and known hypersensitivity to imidazoles or other vaginal antifungal products.
- Irregular vaginal bleeding, abnormal vaginal bleeding or a blood-stained discharge and 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 and diarrhoea.

Dazole mouth paint is not indicated for treatment of systemic candidiasis. Avoid contact with the eyes. Do not use in children under 3 years of age except under the advice and supervision of a doctor. Keep out of the reach of children. Use cautiously in children, pregnant women and nursing women.

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.

Adverse reactions.

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.

Overdose

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).

Presentation.

Pessaries: Blister pack of 1 x 6's in unit carton with applicator.

Mouth paint: A well labelled 15ml plastic dropper bottle in a unit box.

Storage instructions.

Store in a dry place, below 30°C. Protect from direct sunlight.

Keep out of reach of children.

Manufactured By:



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