NAME OF MEDICINE

Active ingredient: Clotrimazole 20mg/g (2%)

Chemical name: 1-(O-chloro-alpha,alpha-diphenylbenzyl) imidazole.

Structural formula:

Molecular formula: C_{22}H_{17}ClN_{2}.  
Molecular weight: 344.84
CAS Registry No.: 23593-75-1

DESCRIPTION

Clotrimazole is a white to pale yellow crystalline powder, practically insoluble in water, soluble in chloroform and ethanol.

Clonea Clotrimazole Thrush Treatment 3 Day Cream contains clotrimazole 20 mg/g (2%). It also contains the following excipients: propylene glycol, disodium edetate, cetomacrogol 1000, cetostearyl alcohol, liquid paraffin, dimethicone 100, white soft paraffin, self-emulsifying glyceryl monostearate, benzyl alcohol, purified water.

PHARMACOLOGY

Clotrimazole is an imidazole antifungal agent and interacts with the cell membrane of sensitive fungi altering its permeability and eventually causing the activation of autolytic enzymes. A single course of intravaginal clotrimazole is usually required to produce mycological cure of vaginal candidiasis. A second course may be required if the first course is unsuccessful. However, other pathogens should be considered and investigated before a second course is commenced. Topical clotrimazole penetrates the epidermis but there is little systemic absorption and slight absorption from the vagina.
Clotrimazole inhibits Candida albicans and, in in vitro studies, Blastomyces dermatitis, Candida spp, Coccidioides immitis, Cryptococcus neoformans (Torula histolytica), dermatophytes (Trichophyton, Microsporum, Epidermophyton), Histoplasma capsulatum, Nocardias spp (less sensitive than true fungi), Paracoccidioides brasiliensis, Sporothium schenckii. Clotrimazole has little or no activity against Haemophilus vaginalis or Trichomonas vaginalis.

**INDICATIONS**

Clotrimazole is indicated for the effective treatment of vaginal candidiasis and relief of associated symptoms such as itching, burning and vaginal discharge.

**CONTRAINDICATIONS**

Known hypersensitivity to clotrimazole or any of the ingredients listed under DESCRIPTION. Not for ophthalmic use.

**PRECAUTIONS**

Not intended for use in the mouth. Local irritation and contact dermatitis may occur.

**Use in Pregnancy (Category A)**

These are drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

However, in the first trimester of pregnancy, clotrimazole vaginal cream should only be used if considered essential. Administration in the second and third trimesters of pregnancy has not produced any untoward effects on the course of the pregnancy or on the fetus.

In the third trimester of pregnancy, extreme caution should be observed when using applicators due to the risk of rupturing the membranes and inducing miscarriage or premature birth, or introducing infection. Using pessaries without an applicator is recommended during the third trimester.

**Use in Lactation**

Use of this product during lactation is acceptable. Please contact your doctor for further advice.

**Carcinogenesis, Mutagenesis and Impairment of Fertility**

An 18 month study has not revealed any carcinogenic effect. Clotrimazole has no mutagenic effect.

**INTERACTIONS WITH OTHER MEDICINES**

Synergism or antagonism between clotrimazole and nystatin, or amphotericin B, or elucytosine against strains of C. albicans has not been reported.
ADVERSE EFFECTS

Generally well tolerated after local application. Erythema, stinging, blistering, peeling, oedema, pruritus, urticaria and general irritation have been reported infrequently. There have been rare reports of mild burning, skin rash and lower abdominal cramps and burning or slight irritation in the sexual partner.

DOSAGE AND ADMINISTRATION

5 g intravaginally using the applicator once daily at bedtime for three successive days inserted as deeply as possible into the vagina with the patient lying down on her back. May also be used in the management of candidal vulvovaginitis or infection of the perianal area. Application to the glans penis of the partner may help prevent reinfection of the female. Treatment during menstruation should be avoided.

The use of latex products such as condoms and diaphragms for contraception is not recommended during treatment with this medicine as some excipients in this medicine may damage the integrity of the condom or diaphragm. This effect is temporary and occurs only during treatment.

This medicine is not recommended for use in children and adolescents under 18 years of age unless on medical advice.

OVERDOSAGE

Acute overdosage with either vaginal or topical application of clotrimazole is unlikely and not expected to be life threatening.

PRESENTATION AND STORAGE CONDITIONS

Vaginal cream 20 mg/g (2%)
20 g tube (3 applicators provided).

Store below 25°C.

NAME AND ADDRESS OF THE SPONSOR

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POISONS SCHEDULE OF THE MEDICINE

S3- Pharmacist Only Medicine

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG):

21 November 2014