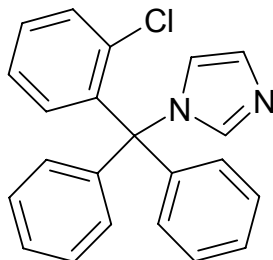


**APO-CLOTRIMAZOLE 3 DAY CREAM
APO-CLOTRIMAZOLE 6 DAY CREAM****NAME OF THE MEDICINE**

Clotrimazole.

Chemical Name: 1-(o-chloro- α,α -diphenylbenzyl) imidazole

Chemical Structure:



Molecular Formula: $C_{22}H_{17}ClN_2$

Molecular Weight: 344.84

CAS Registry Number: 23593-75-1

DESCRIPTION

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

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*, *Nocardia* spp (less sensitive than true fungi), *Paracoccidioides brasiliensis*, *Sporotrichum schenckii*.

Clotrimazole has little or no activity against *Haemophilus vaginalis* or *Trichomonas vaginalis*.

INDICATIONS

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 excipients.
- Not for ophthalmic use.

PRECAUTIONS

Clotrimazole vaginal cream is for intravaginal use only and is not to be taken orally.

Local irritation and contact dermatitis may occur.

Carcinogenesis, mutagenesis, impairment of fertility

An 18-month study has not revealed any carcinogenic effect.

Clotrimazole has no mutagenic effect.

Use in Pregnancy (Category A)

Category A – definition : drugs which have been taken by a large number of pregnant women and women of child-bearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

In the first trimester of pregnancy, clotrimazole should only be used when the medical practitioner considers it essential for the welfare of the patient.

Administration in the second and third trimester of pregnancy has not produced any untoward effects on the course of the pregnancy or on the foetus.

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

Although systemic absorption following vaginal administration is low, caution should be exercised when clotrimazole is administered to nursing mothers as there is no information on whether or not clotrimazole is excreted in breast milk.

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.

Interaction with Barrier Contraceptives

The mineral oil in this cream may weaken condoms or vaginal contraceptive diaphragms and reduce their effectiveness. It is recommended that these contraceptives are not used whilst using this cream, and for 72 hours after the end of treatment.

ADVERSE EFFECTS

Clotrimazole cream is 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

The cream (5 g) should be inserted as deeply as possible into the vagina once daily, at bedtime – for three successive days if using Apo-Clotrimazole 3 Day Cream, or six consecutive days if using Apo-Clotrimazole 6 Day Cream. This is best achieved using the plastic applicator provided and following the directions in the Consumer Medicine Information.

It is suggested that treatment be timed so as to avoid the menstrual period and to be complete before the onset of menstruation.

The clotrimazole cream may also be used in the management of Candida vulvovaginitis or infection of the perianal area, while application of the cream to the glans penis of the partner may help prevent re-infection of the female.

OVERDOSAGE

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

Contact the Poison Information Centre on 13 11 26 (Australia) for advice on the management of overdosage.

PRESENTATION AND STORAGE CONDITIONS

Apo-Clotrimazole 3 Day Cream (20 g):
Soft, shiny, white cream.
AUST R 150662.
Tube with 3 single use disposable applicators.

Apo-Clotrimazole 6 Day Cream (35 g):
Soft, shiny, white cream.
AUST R 150663
Tube with 6 single use disposable applicators.

Apo- GenRx Clotrimazole 3 Day Cream contains 20 mg/g (2% w/w) clotrimazole.

Apo- GenRx Clotrimazole 6 Day Cream contains 10 mg/g (1% w/w) clotrimazole.

In addition the creams also contain propylene glycol, disodium edetate, cetomacrogol 1000, cetostearyl alcohol, liquid paraffin, dimethicone 100, white soft paraffin, self emulsifying glyceryl monostearate, benzyl alcohol and purified water.

Storage Conditions

Store below 25°C.

NAME AND ADDRESS OF THE SPONSOR

Apotex Pty Ltd
ABN 52 096 916 148
66 Waterloo Road
North Ryde NSW 2113
Australia

Apotex Pty Ltd. is the licensee of the registered trade marks AX logo, APO and APOTEX from the registered proprietor, Apotex Inc.

POISON SCHEDULE OF THE MEDICINE

Pharmacist Only Medicine : S3

Date of TGA approval:

Apo-Clotrimazole 3 Day Cream: 21 February 2008

Apo-Clotrimazole 6 Day Cream: 29 February 2008

Date of most recent amendment: 14 September 2009