

AUSTRALIAN PRODUCT INFORMATION

CLONEA CLOTRIMAZOLE THRUSH TREATMENT 3 DAY CREAM

Clotrimazole vaginal cream

1 NAME OF THE MEDICINE

Clotrimazole

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clonea Clotrimazole Thrush Treatment 3 Day Cream contains clotrimazole 20 mg/g (2%).

Excipients with known effect: benzyl alcohol 1% w/w (as a preservative).

For the full list of excipients, see **Section 6.1 LIST OF EXCIPIENTS**.

3 PHARMACEUTICAL FORM

Vaginal cream, clotrimazole 20 mg/g (2%): white, smooth semi-solid cream

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

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

4.2 DOSE AND METHOD OF 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.

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

4.3 CONTRAINDICATIONS

Known hypersensitivity to clotrimazole or any of the ingredients listed under **Section 6.1 LIST OF EXCIPIENTS**. Not for ophthalmic use.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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

Interactions with Latex

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.

Use in the Elderly

No data available.

Paediatric Use

No data available.

Effects on Laboratory Tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

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

4.6 FERTILITY, PREGNANCY AND LACTATION**Effects on Fertility**

No data available.

Use in Pregnancy

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.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE 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.

Reporting Suspected Adverse Effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Acute overdosage with either vaginal or topical application of clotrimazole is unlikely and not expected to be life threatening. For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of Action

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

Clinical Trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

Clotrimazole has no mutagenic effect.

Carcinogenicity

An 18 month study has not revealed any carcinogenic effect.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Clonea Clotrimazole Thrush Treatment 3 Day Cream contains the following excipients: propylene glycol, disodium edetate, cetomacrogol 1000, cetostearyl alcohol, liquid paraffin, dimeticone 100, white soft paraffin, self-emulsifying glyceryl monostearate, benzyl alcohol, purified water.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Container type: Cream tube (3 applicators provided)
Pack size: 20 g

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking it to your local pharmacy.

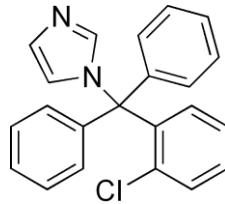
6.7 PHYSICOCHEMICAL PROPERTIES

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

Chemical Structure

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

Structural formula:



Molecular formula: C₂₂H₁₇ClN₂.

Molecular weight: 344.84

CAS Number

23593-75-1

7 MEDICINE SCHEDULE (POISONS STANDARD)

S3 (Pharmacist Only Medicine)

8 SPONSOR

Cipla Australia Pty Ltd

Level 1 / 132-136 Albert Road,
SOUTH MELBOURNE VIC 3205

drugsafety@cipla.com

Phone no: 1800 569 074

9 DATE OF FIRST APPROVAL

21/11/2014

10 DATE OF REVISION

04/05/2022

Summary Table of Changes

| Section Changed | Summary of New Information |
|-----------------|----------------------------|
| 8 | Updated sponsor details |