AUSTRALIAN PRODUCT INFORMATION

CLONEA CLOTRIMAZOLE THRUSH TREATMENT 6 DAY CREAM

Clotrimazole vaginal cream

1 NAME OF THE MEDICINE

Clotrimazole

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clonea Clotrimazole Thrush Treatment 6 Day Cream contains clotrimazole 10 mg/ g (1%).
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 10 mg/g (1%): white, smooth semi-solid cream

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

A broad spectrum antifungal for the effective treatment of vaginal candidiasis (commonly referred to as thrush) and the relief of the associated symptoms such as itching, burning and vaginal discharge.

4.2 DOSE AND METHOD OF ADMINISTRATION

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

4.3 CONTRAINDICATIONS

Known hypersensitivity to clotrimazole or any of the excipients.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Local irritation and contact dermatitis may occur.

If evidence of local intolerance develops, consider withdrawal of the drug and institution of appropriate therapy.

This medicine is for intravaginal use only and is not to be taken orally. Avoid contact with eyes.

A doctor should be consulted before use in the following circumstances:

- If it is the first occurrence of the problem
- If there have been three or more thrush infections in the previous six months
- If pregnant
- If diabetic

- If under 18 years of age
- If not better in four days

If the patient has a fever (temperature of 38°C or above), lower abdominal pain, back pain, foul smelling vaginal discharge, nausea, vaginal haemorrhage, and/or associated shoulder pain the patient should consult a doctor.

If symptoms persist for more than 4 days the patient may have a medical condition that requires treatment by a doctor.

The treatment can be repeated if necessary, however, recurrent infections may indicate an underlying medical cause, including diabetes or HIV infection. Patients should seek medical advice if symptoms return within 2 months.

Since the vagina and vulva are usually both affected, a combination treatment (treatment of both of these areas) should be performed.

lf the labia and adjacent areas are simultaneously infected, local treatment with an external cream should also be given. The sexual partner should also undergo local treatment if symptoms, e.g. pruritus, inflammation, etc. are present.

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

Do not use tampons, intravaginal douches, spermicides or other vaginal products while using this medicine.

Avoidance of vaginal intercourse is recommended while using this product because the infection could be transferred to the partner, and the effectiveness and safety of latex products such as condoms and diaphragms may be reduced (see **Interactions with Latex**).

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.

Concomitant medication with vaginal clotrimazole and oral tacrolimus (FK-506, an immunosuppressant) might lead to increased tacrolimus plasma levels. Patients should thus be thoroughly monitored for symptoms of tacrolimus overdosage, if necessary by determination of the respective plasma levels.

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

Although systemic absorption following topical or 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.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No effects on ability to drive and use machines have been observed.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Generally well tolerated after local application. Erythema, stinging, blistering, peeling, oedema, prutitis, urticaria and general irritation have been reported infrequently. There have been rare reports of mild burning, skin rash and lower abdominal cramps 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 overdose 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 alternating 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 recommended. Topical clotrimazole penetrates the epidermis but there is little systemic absorption and slight absorption from the vagina.

Clotrimazole is a broad spectrum antifungal agent that inhibits most pathogenic fungi especially Candida albicans. Its spectrum of antifungal activity includes the following pathogens: Blastomyces dermatitidis, Candida spp, Coccidiodes immitis, dermatophytes (Trichophyton, Microsporum, Epidermophyton), Histoplasma capsulatum, Paracoccidiodes brasiliensis and only some strains of Cryptococcus neoformans and Sporotrichum schenekii. 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

No mutagenicity has been observed in animal studies.

Carcinogenicity

No carcinogenicity has been observed in animal studies.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Clonea Clotrimazole Thrush Treatment 6 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 and 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 (6 applicators provided)
Pack size: 35 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.

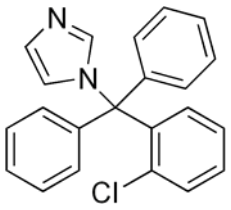
6.7 PHYSICOCHEMICAL PROPERTIES

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-α,α- diphenylbenzyl) imidazole

Structural formula:



Molecular formula: $C_{22}H_{17}ClN_2$ Molecular weight: 344.84

CAS Number

23593-75-1

7 MEDICINE SCHEDULE (POISONS STANDARD)

S3 (Pharmacist Only Medicine)

8 SPONSOR

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9 DATE OF FIRST APPROVAL

18/01/2016

10 DATE OF REVISION

04/05/2022

Summary Table of Changes

Section Changed	Summary of New Information
8	Updated sponsor details

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