Clonea

Clotrimazole

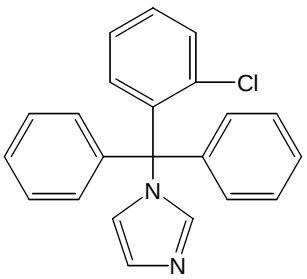
PRODUCT INFORMATION

Name of the Medicine

The active ingredient of Clonea cream is Clotrimazole.

Chemical name: 1-(o-chloro-α,α-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 an odourless, white, crystalline powder, almost insoluble in water, slightly soluble in ether and soluble in carbon tetrachloride, ethanol and chloroform. Its melting point is 141°C to 145°C. Clotrimazole is not light sensitive, only mildly hygroscopic and is slowly hydrolysed in a strongly acid medium. It forms stable salts with both organic and inorganic acids.

Each gram of Clonea contains clotrimazole 10 mg (1%) in a vanishing cream base of sorbitan monostearate, polysorbate 60, cetyl esters wax, cetostearyl alcohol, octyldodecanol, purified water and, as a preservative, benzyl alcohol (2.4%).

Pharmacology

Clotrimazole, the active ingredient of Clonea, is an imidazole derivative with a broad spectrum antimycotic activity. The primary mode of action of clotrimazole appears to be on the cell membrane of the fungi, damaging the permeability barrier.

Pharmacokinetic investigations after dermal application have shown that only a small amount of clotrimazole (< 2 % of the dose) is absorbed. The resulting peak plasma concentrations of the active ingredient are < 10 nanogram/mL (*i.e.,* below the detection limit) and do not lead to measurable systemic effects or side effects.

Following an application to the skin, the highest levels of clotrimazole can be found in the stratum corneum. Lower concentrations of the drug occur in the stratum spinosum and the papillary and reticular dermis.

Studies of urinary excretion have shown that less than 0.5% of dermally applied clotrimazole cream appears in the urine over a five-day period of observation. No study on faecal excretion, by which most of the absorbed drug is likely to be eliminated, has been done in humans.

Indications

Topical treatment of the following cutaneous infections: tinea pedis, tinea cruris and tinea corporis due to *Trichophyton rubrum, Trichophyton mentagrophytes, Epidermophyton floccosum* and *Microsporum canis*; candidiasis (moniliasis) caused by *Candida albicans* including cutaneous candidiasis, paronychia, external genital candidiasis, candidal balanitis; pityriasis versicolor due to *Malassezia furfur*; erythrasma.

Contraindications

Individuals who have shown hypersensitivity to clotrimazole, or any other imidazole, or any component of the cream.

Precautions

If a patient shows no clinical improvement after four weeks of treatment with Clonea, the diagnosis should be reviewed.

If irritation or sensitivity develops with the use of Clonea, treatment should be discontinued and appropriate therapy instituted.

Overgrowth of non-susceptible organisms may occur with prolonged use of any microbial agent.

Clonea cream is not for ophthalmic use.

Carcinogenesis and mutagenesis

No carcinogenicity or mutagenicity has been observed in animal studies.

Use in Pregnancy (Category A)

Clotrimazole has been used by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of foetal malformations or other direct or indirect harmful effects on the foetus having been observed.

However, because no control study has been conducted, Clonea should be used in pregnancy only when considered essential to the welfare of the patient.

Use in Lactation

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

Effects on laboratory tests

None known.

Interactions with Other Medicines

No drug interactions have been reported with topical forms of clotrimazole.

Adverse Effects

Clonea anti-fungal cream is well tolerated after local application. The following have been reported infrequently: erythema, stinging, blistering, peeling, oedema, pruritus, urticaria and general irritation.

Dosage and Administration

Clonea cream should be applied sparingly and rubbed gently into cleansed, affected area and surrounding skin in the morning and evening. Improvement and relief of pruritus usually occurs within 1 week. However, therapy may need to be extended for up to 8 weeks for mycological cures especially if treating tinea pedis. If improvement is not seen within 4 weeks of treatment, the diagnosis should be re-evaluated.

Tinea cruris should usually be treated for 2 weeks; cutaneous candidiasis for 2 weeks; dermatomycoses for 2 to 4 weeks; onychia and paronychia due to *C. albicans* for 4 to 8 weeks or more; and tinea pedis or corporis for 4 weeks.

If an adequate improvement is not observed, the drug should be discontinued and a physician or pharmacist consulted.

Regular application of Clonea Clotrimazole Cream is essential for successful treatment and, whether or not a cure is confirmed mycologically, treatment should be continued for two weeks after all clinical signs have disappeared.

Note. Attention to hygiene is important in the management of fungal diseases of the feet; after washing, the feet, especially between the toes, should be dried thoroughly. Clonea cream may be useful in mycotic paronychia or onychia following removal of the nail.

Overdosage

Since application of ^{14}C-labelled clotrimazole to intact or diseased skin under occlusive dressing for six hours did not yield measurable quantities (lower detection limit 0.001 microgram/mL) of radioactive material in the sera of human subjects, overdosage by topical administration is highly improbable.

If accidentally ingested it not likely to be harmful. However, in cases of overdosage, it is advisable to contact the Poisons Information Centre (131126) for recommendation on the management and treatment of overdosage.

Information for Patients

Use medication for the full treatment time even though the symptoms may have improved. When symptoms disappear, make sure to continue treatment for another 14 days so that the underlying (non-visible) infection can be eradicated.

Consult your physician if there is no improvement after 4 weeks of treatment. Inform the physician if the area of application shows signs of increased irritation (redness, itching, burning, blistering, swelling, oozing-indicative of possible sensitivity).

Use a separate towel to dry the infected area to prevent spreading of infection to other body areas. Avoid sources of potential infection and reinfection.

Presentation and Storage Conditions

Clonea, 1% w/w (i.e. 10 mg/g) clotrimazole cream: smooth, white; 20 g, 50 g.

Store below 25 ºC.

Poison Schedule of the Medicine

S2 Pharmacy only Medicine

Name and Address of the Sponsor

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Date of Approval

Approved by the Therapeutic Goods Administration on 8 February 2005.

Date of most recent amendment: 5 January 2007.