

CLOMAZOL

Clomazol vaginal cream, 3 Day Treatment (vaginal cream 2%)

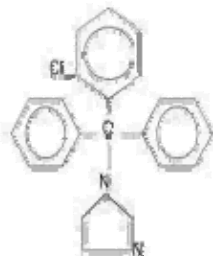
Clomazol vaginal cream, 6 Day Treatment (vaginal cream 1%)

Clomazol Topical Cream 1%

Name of Medicine

Clotrimazole

1-(o-chloro- α , α - diphenylbenzyl) imidazole



$C_{22}H_{17}ClN_2$

Molecular Weight 344.84

Clotrimazole is a colourless, crystalline, weakly alkaline substance, melting point 141°-145°C, soluble in acetone, chloroform and ethanol and practically insoluble in water. It forms stable salts with both organic and inorganic acids. It is not photosensitive but is slightly hygroscopic, and may be hydrolysed in acid media.

Description

Clomazol vaginal cream 3 Day treatment

Clomazol 3 Day vaginal cream contains 20 mg/g (2% w/w) of clotrimazole in a cream base. The cream also contains glycerol monostearate, cetostearyl alcohol, benzyl alcohol (1% w/w), disodium edetate, cetomacrogol, propylene glycol, liquid paraffin, dimeticone, white soft paraffin and purified water.

Clomazol vaginal cream 6 Day treatment

Clomazol 6 Day vaginal cream contains 10 mg/g (1% w/w) of clotrimazole in a cream base. The cream also contains glycerol monostearate, cetostearyl alcohol, benzyl alcohol (1% w/w), disodium edetate, cetomacrogol, propylene glycol, liquid paraffin, dimeticone, white soft paraffin and purified water.

Clomazol Topical Cream

Clomazol Topical Cream contains 10 mg/g (1%) of clotrimazole in a cream base. The cream also contains glycerol monostearate, cetostearyl alcohol, benzyl alcohol (1% w/w), disodium edetate, cetomacrogol, propylene glycol, liquid paraffin, dimeticone, white soft paraffin and purified water.

Pharmacology

Clotrimazole cream containing ^{14}C -labelled clotrimazole was administered intravaginally to five women (four without gynaecological disorder and one with *Candida* vaginitis). A maximum serum level of $0.01\ \mu\text{g}/\text{mL}$ was found between 10 and 30 hours after administration.

Six hours after application of labelled topical clotrimazole cream the concentrations of clotrimazole ranged from $100\ \mu\text{g}/\text{cm}^3$ in the stratum corneum to $0.05 - 1.0\ \mu\text{g}/\text{cm}^3$ in the stratum reticulare and $0.1\ \mu\text{g}/\text{cm}^3$ in the subcutis.

No measurable radioactivity was found in the serum within 48 hours after application of 0.8 g of the cream.

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. Faecal excretion, the route by which most of the absorbed medicine is likely to be eliminated, has not been studied in man.

The primary mode of action of clotrimazole cream appears to be on the cell membrane of the fungi, damaging the permeability barrier.

A single course of intravaginal clotrimazole cream has produced mycological cure of vaginal candidiasis as follows:

5 g of 1% cream daily for six days approx. 75%

When a first course proved unsuccessful, a second course produced success in 8 of 12 women treated.

Indications

Clomazol 3 Day and 6 Day vaginal creams are indicated for the topical treatment of vulvovaginal candidiasis. Application of the cream to the glans penis of the partner may help prevent re-infection of the female.

Clomazol topical cream is indicated for the topical treatment of the following dermal infections:

1. Tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis (ringworm of the trunk and limbs) due to *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Epidermophyton floccosum* and *Microsporum canis*.
2. Candidiasis due to *Candida albicans* including cutaneous candidiasis, onychia (infection of the nail or nail bed), paronychia (infection of the nail fold), external genital candidiasis, candida balanitis (*Candida* in the male genital area), nappy rash.
3. Pityriasis versicolor due to *Malassezia furfur*.
4. Erythrasma (a chronic skin infection due to the bacterium *Corynebacterium minutissimum*).

Contraindications

Known hypersensitivity to clotrimazole and/or to any of the excipients.

Precautions

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

Clomazol creams are not intended for ophthalmic use.

Carcinogenicity/Mutagenicity

No carcinogenicity or mutagenicity has been observed in animal studies.

Use in Pregnancy (Category A)

While controlled clinical studies in pregnant women do not exist, epidemiological investigations give no indications that harmful effects on the mother and child should be anticipated when clotrimazole is used during pregnancy. However, as with all medicines in the first three months of pregnancy, clotrimazole should only be used after first consulting a doctor.

Sanitation of the birth canal should be ensured particularly during the last 4 – 6 weeks of pregnancy.

Use in Lactation

Because systemic absorption of clotrimazole following topical or vaginal application is marginal, there should be no risk for the infant during lactation.

Interactions with other Medicines

Not reported with topical forms of clotrimazole.

Effects on Laboratory Tests

Not known.

Interactions with Latex

Clomazol vaginal cream may reduce the effectiveness and safety of latex products, such as condoms and diaphragms. This effect is temporary and occurs only during treatment.

Adverse Reactions

Clotrimazole creams are generally well tolerated after local application. The following have been reported infrequently: erythema, stinging, blistering, peeling, oedema, pruritus, urticaria and general irritation.

Dosage And Administration

Clomazol vaginal cream 6 Day treatment (vaginal cream 1%)

Once daily, preferably in the evening for six successive days, one applicator should be filled with cream (approx. 5 g) and inserted as deeply as possible into the vagina with the patient lying on her back. The 35 g tube of cream for vaginal use provides for six such doses.

Clomazol vaginal cream 3 Day treatment (vaginal cream 2%)

Once daily, preferably in the evening for three successive days, one applicator should be filled with cream (approx. 5 g) and inserted as deeply as possible into the vagina with the patient lying on her back. The 20 g tube of cream for vaginal use provides for three such doses.

Clomazol Topical Cream

Apply sparingly to the affected areas and rub in gently, two or three times daily.

Duration of treatment

The following recommendations are made:

Cutaneous candidiasis 2 weeks

Dermatomycoses 2-4 weeks

Onychia and Paronychia
due to *C. albicans* 4-8 weeks or more

Regular application of Clomazol topical 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.

Special remarks

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. Clotrimazole cream may be useful in mycotic paronychia or onychia following removal of the nail.

Overdosage

Not applicable.

Presentations and Pack Sizes

Clomazol vaginal cream 3 Day treatment (vaginal cream 2%)

One tube containing 20 g of cream, 20 mg clotrimazole per gram (2% w/w) packed with three single-use disposable applicators and patient instruction sheet.

Clomazol vaginal cream 6 Day treatment (vaginal cream 1%)

One tube containing 35 g of cream, 10 mg clotrimazole per gram (1% w/w) packed with six single-use disposable applicators and patient instruction sheet.

Clomazol Topical Cream

Packs of one tube containing 20 g of cream, 10 mg clotrimazole per gram (1% w/w).

Medicine Classification

Pharmacist Only Medicines

Clomazol vaginal cream

- 3 Day Cream
- 6 Day Cream

Pharmacy Medicines

Clomazol

- Topical Cream

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