

## Clotrimazole and betamethasone

**Introduction:** Clotrimazole Betamethasone Cream is an antifungal and corticosteroid combination.

**Mechanism of action:** Clotrimazole—Fungistatic, may be fungicidal, depending on concentration. Inhibits biosynthesis of ergosterol or other sterols, damaging the fungal cell wall membrane and altering its permeability. As a result, leakage of intracellular phosphorus compounds with accompanying breakdown of cellular nucleic acids and accelerated potassium efflux occurs. Clotrimazole also inhibits biosynthesis of triglycerides and phospholipids by fungi. In addition, it inhibits oxidative and peroxidative enzyme activity, resulting in intracellular buildup of toxic concentrations of hydrogen peroxide, which may contribute to deterioration of subcellular organelles and cellular necrosis. Betamethasone dipropionate—Mechanism of betamethasone dipropionate's dermatological action is unclear. However, corticosteroids diffuse across cell membranes and complex with specific cytoplasmic receptors. These complexes then enter the cell nucleus, bind to DNA (chromatin), and stimulate transcription of messenger RNA (mRNA) and subsequent protein synthesis of various enzymes thought to be ultimately responsible for the anti-inflammatory effects. Betamethasone dipropionate is effective in treating inflamed dermatoses because of its anti-inflammatory, antipruritic, and vasoconstrictive actions.

**Indications:** Clotrimazole Betamethasone Cream is indicated in patients 17 years and older for the topical treatment of symptomatic inflammatory tinea pedis, tinea cruris, and tinea corporis due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, and *Trichophyton rubrum*. Effective treatment without the risks associated with topical corticosteroid use may be obtained using a topical antifungal agent that does not contain a corticosteroid, especially for noninflammatory tinea infections. The efficacy of Clotrimazole Betamethasone Cream for the treatment of infections caused by zoophilic dermatophytes (eg, *Microsporum canis*) has not been established. Several cases of treatment failure of Clotrimazole Betamethasone Cream in the treatment of infections caused by *Microsporum canis* have been reported.

**Dosage:** Gently massage sufficient Clotrimazole Betamethasone Cream into the affected skin areas twice a day, in the morning and evening.

**Side effects:** Local redness, stinging, blistering, peeling, swelling, itching, hives, and burning at the area of application may occur. Other side effects associated with Clotrimazole Betamethasone Cream include water retention (edema), decreased pigmentation, stretch marks and infection due to bacteria. Growth retardation, intracranial hypertension, Cushing's syndrome and skin atrophy have occurred in pediatric patients.

**Precautions:**

**General:** Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Patients applying Clotrimazole Betamethasone Cream to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, morning plasma cortisol, and urinary-free cortisol tests.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation develops, Clotrimazole Betamethasone Cream should be discontinued and appropriate therapy instituted.

**Pregnancy Teratogenic Effects Pregnancy Category C:** Clotrimazole Betamethasone Cream should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Nursing Mothers:** It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when Clotrimazole Betamethasone Cream is administered to a nursing woman.

**Pediatric Use:** Adverse events consistent with corticosteroid use have been observed in patients under 12 years of age treated with Clotrimazole Betamethasone Cream. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

**Geriatric Use:** Caution should be exercised with the use of these corticosteroid-containing topical products on thinning skin.

**Contraindications:** Clotrimazole Betamethasone Cream is contraindicated in patients who are sensitive to clotrimazole, betamethasone dipropionate, other corticosteroids or imidazoles, or to any ingredient in these preparations.

**How supplied: Customized as per request.**