

TRANSLIPO-3 CREAM

COMPOSITION

Each gram contains:	
Clotrimazole	1 % w/w
Neomycin	0.5 % w/w
Beclomethasone Dipropionate	0.025 % w/w
in a Translipid cream base	

DESCRIPTION

Translipo-3 Cream contains the active compound Beclomethasone dipropionate (a synthetic corticosteroid), Clotrimazole and Neomycin for topical dermatologic use.

Beclomethasone dipropionate is an anti-inflammatory, synthetic, halogenated steroid having the chemical name, 9-Chloro-11(beta), 17,21-trihydroxy-16(beta)-methylpregna-1, 4-diene-3, 20-dione 17,21-dipropionate.

Clotrimazole, an imidazole antifungal drug, for topical use in superficial fungal infections is chemically designated as 1-(alpha-2-Chlorotriptyl) imidazole.

Neomycin sulphate, an aminoglycoside antibiotic, is the sulphate salt of neomycin B and C, produced by the growth of *Streptomyces fradiae*.

Translipid cream base is a unique combination of 70% lipids dispersed in 30% water. It spreads better, helps the active ingredient to stay longer and penetrate faster, giving the power of an ointment with the comfort of a cream.

CLINICAL PHARMACOLOGY

Pharmacodynamics

Beclomethasone 17,21-dipropionate is a diester of beclomethasone which has potent glucocorticosteroid and weak mineralocorticosteroid activity. The mechanism for the anti-inflammatory action of beclomethasone dipropionate is unknown. It is postulated that topical steroids control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Corticosteroids are also thought to act by the induction of phospholipase A2 inhibitory proteins.

Clotrimazole exerts antifungal effects by inhibition of fungal sterol synthesis. It appears to inhibit the enzymatic conversion of 2,4-methylenedihydrolanosterol to demethylsterol, the precursor to ergosterol, which is an essential building block of the cytoplasmic membrane of the fungi. Clotrimazole is a broad spectrum antifungal agent that inhibits the growth of most fungi pathogenic to man, including the *Candida* and *Dermatophytes* (*Trichophyton*, *Microsporum*, *Epidermophyton*).

Neomycin acts on bacteria by interfering with bacterial protein synthesis by binding to 30s ribosomes. The antibacterial spectrum of Neomycin includes specific organisms which are susceptible to it and generally includes all medically important aerobic gram negative bacilli except *Pseudomonas aeruginosa*. Anaerobic bacteria are resistant. *Staphylococcus aureus* and *Staph. epidermidis* are highly sensitive, but all streptococci are relatively resistant.

Pharmacokinetics

Topical corticosteroids can be absorbed from normal intact skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors,

including the vehicle and the integrity of the epidermal barrier. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Systemic absorption following use of topical Clotrimazole preparations is very low. Estimated bioavailability is less than 0.5%. Clotrimazole concentrations achieved in the epidermal layers exceed the minimal inhibitory concentrations (MICs) for almost all pathogenic fungi.

INDICATIONS & USAGE

Translipo-3 Cream is indicated for the relief of the inflammatory manifestations of corticosteroid responsive dermatoses when complicated by secondary infection caused by organisms sensitive to the components of this dermatologic preparation or when the possibility of such infection is suspected.

Such disorders include: Chronic dermatitis of the extremities, balanoposthitis, eczematoid dermatitis, contact dermatitis, follicular dermatitis, parakeratosis, paronychia, anal pruritus, intertrigo, impetigo, neurodermatitis, angular stomatitis, photosensitivity dermatitis, lichenified inguinal dermatophytosis and tinea infections such as tinea pedis, tinea cruris and tinea corporis.

As with other highly active corticosteroids, therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary.

CONTRAINDICATIONS

Translipo-3 Cream is contraindicated in those patients with a history of sensitivity reactions to any of its components.

Use in pediatric patients under 12 years of age is not recommended.

ADVERSE REACTIONS

The most frequent adverse reactions reported were burning, irritation, itching and stinging sensation. Less frequent adverse reactions were skin atrophy, cracking and fissuring of the skin, erythema, folliculitis, numbness of fingers, skin atrophy and telangiectasia.

The following additional local adverse reactions have been reported occasionally with topical corticosteroids: dryness, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae, and miliaria.

Neomycin occasionally causes skin sensitization. Ototoxicity and nephrotoxicity have been reported with oral administration.

DOSAGE & ADMINISTRATION

A small quantity of **Translipo-3** Cream should be applied to cover completely the affected area two or three times daily, or as prescribed by the physician. Frequency of application should be determined according to severity of the condition.

Duration of therapy should be determined by patient response. In cases of tinea pedis, longer therapy (2 - 4 weeks) may be necessary.

PRECAUTIONS

Translipo-3 Cream is not for ophthalmic use.

Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal from treatment. Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression.

Manifestations of Cushing syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on therapy.

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

If irritation or sensitization develops with the use of **Translipo-3** Cream, treatment should be discontinued and appropriate therapy instituted.

Prolonged use of topical antibiotics occasionally may result in overgrowth of non-susceptible organisms. If this occurs or if irritation, sensitization or super infection develops, treatment with **Translipo-3** Cream should be discontinued and appropriate therapy instituted.

Carcinogenesis, Mutagenesis, Impairment of Fertility: There was no evidence of carcinogenicity in the study conducted in rats. Studies to assess the mutagenic potential of beclomethasone dipropionate have not been conducted. Impairment of fertility, as evidenced by inhibition of the estrous cycle in dogs, was observed following treatment by the oral route at a dose of 0.5 mg/kg/day.

Pregnancy & Nursing Mothers: Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively in large amounts or for prolonged periods of time in pregnant patients.

Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness of **Translipo-3** Cream in pediatric patients have not been established. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids.

OVERDOSAGE

Symptoms: Excessive or prolonged use of topical corticosteroids can suppress hypothalamic-pituitary-adrenal function, resulting in secondary adrenal insufficiency, and produce manifestations of hypercorticism, including Cushing's disease.

Excessive or prolonged use of topical antibiotics may lead to overgrowth of non-susceptible organisms in lesions.

Appropriate symptomatic treatment is indicated. Acute hypercorticotid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised.

If overgrowth by non-susceptible organisms occurs, stop treatment with **Translipo-3** Cream and institute appropriate therapy.

PRESENTATION

Translipo-3 Cream is available in a tube of 10 g.

STORAGE

Store between 15° and 30° C. **Translipo-3** Cream should not be refrigerated.