

SUMMARY OF PRODUCT CHARACTERISTICS

**PRODUCT NAME: MEDIZONE – CLOTRIMAZOLE +
BETAMETHASONE DIPROPIONATE + NEOMYCIN CREAM**

DOSAGE FORM: Semi-Solid Dosage Form – Cream

THERAPEUTIC CATEGORY – Antifungal, Antibiotic and Anti-inflammatory Cream

COMPOSITION

Clotrimazole BP..... 1.00% w/w
Betamethasone Dipropionate USP Equivalent to
Betamethasone..... 0.05% w/w
Neomycin Sulfate USP 0.50% w/w equivalent to
Neomycin base..... 0.35% w/w
In a cream base.

EXCIPIENTS:

Chlorocresol BP, Cetomacrogol-1000 BP, Cetostearyl Alcohol BP, Light Liquid Paraffin BP, White Soft Paraffin BP, Propylene Glycol BP, Isopropyl Myristate BP, Citric Acid Anhydrous BP, Fragrance Soft Petal AF 1023 BP, Purified Water BP.

PHARMACOLOGY

Pharmacodynamics

Pharmacotherapeutic group: Antifungal, Antibiotic and Anti-inflammatory.

ATC code: Betamethasone Dipropionate: D07AC01, Clotrimazole: D01AC01, Neomycin Sulfate :
D06AX04

Betamethasone is a glucocorticosteroids receptor agonist. This leads to changes in genetic expression once this complex binds to the GRE. The anti-inflammatory actions of corticosteroids are thought to involve lipocortins phospholipase A2 inhibitory proteins which, through inhibits Arachidonic acid, control the biosynthehsis of prostaglandins and leukotrienes.

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 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 and epidermophyton).

Neomyicin 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. Aerobic 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

MEDIZONE cream is indicated for the relief of the inflammation manifestations of corticosteroid response dermatoses when complicated by secondary infection caused by organism sensitive to this components or dermatological preparation or when the possibility of such infection is suspected.

Such disorders include : Chrome dermatitis of the extremities, balanoposthitis, eczematoid dermatitis, contact dermatitis, follicular dermatitis, parakeratosis. anal pruritis. Intertigo, Impetigo neurodermatitis, angular stomatitis, photosensitivity dermatitis, dermatitis. Lichenified inguinal dermatophytosis and linea infections such as tinea pedis, tinea cruns 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

It is contraindicated in those patients with a history of sensitivity reactions to any of its components. Use in paediatric patients under 12 years of age is not recommended.

PRECAUTIONS

If irritation or hypersensitivity develops with the use of the drug, Treatment should be discontinued and appropriate therapy instituted. The use of gentamicin may result in overgrowth of nonsusceptible organisms including fungi. If superinfection occurs during gentamicin therapy, the drug should be discontinued and appropriate therapy instituted.

General systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestation of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. The use of cream for longer than 4 weeks is not recommended.

Pregnancy and lactation

Pregnancy

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.

Breast-feeding

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. It is not for ophthalmic use. Systemic absorption of topical corticosteroid 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 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. Paediatric patients may

be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratio. Irritation or sensitization develops with the use of this cream. Treatment should be discontinued and appropriate therapy instituted. Prolonged use of topical antibiotics occasionally may result in overgrowth or non-susceptible organisms. If this occurs or irritation, sensitization or super infection develops, treatment with this Cream should be discontinued and appropriate therapy instituted.

INTERACTIONS WITH OTHER MEDICINES

Betamethasone

Betamethasone is known to interact with other drugs like Amphotencin B. carbamazepine lofexidine, metyrosine, oxandrolone, perindopril, phenytoin (Na), rifampicin. Always consult your physician for the change of dose regimen or an alternative drug of choice that may strictly be required.

Clotrimazole

Clotrimazole is known to interact with other drugs like aliskiren. Always consult your physician for the change of dose regimen or an alternative drug of choice that may strictly be required.

Neomycin

Neomycin is known to interact with other drugs like acarbose, atracurium (Besylate), cyanocobalamine digoxin Doxacurium, Fluorouracil, gentamicin, gestodene. hydroxocobalamin, mecobalamine, Methotrexate, pancuronium (Br). Always consult your physician for the change of dose.

ADVERSE EFFECTS

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

The following additional local adverse reactions have been reported occasionally with topical corticosteroids, dryness. Acneiform eruptions, hypo pigmentation, allergic contact dermatitis, secondary infections, stnae and miliaria. Neomycin occasionally causes skin sensitization. Ototoxicity nephrotoxicity have been reported with oral administration.

DOSAGE AND ADMINISTRATION

It 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.

SYMPTOMS AND TREATMENT OF 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 disease. Excessive or prolonged use of topical antibiotics may lead to overgrowth of non-susceptible organisms in lesions. Appropriate symptomatic treatment is indicated. Acute hyper corticoid 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 this Cream and institute appropriate therapy.

STORAGE

Do not store above 30°C. Protect from light.

Keep the medicine out of reach of children.

PRESENTATION

30g in Collapsible Aluminium tube lacquered with epoxy phenol. 1 such tube in a printed carton with a printed insert.

30g in Lami tube with Alu peel off seal. 1 such tube in a printed carton with a printed insert.

MADE IN INDIA

S KANT HEALTHCARE LTD.