

# MEDIHIST

**Cream**

## Composition

Each 100 gm contains:

Clotrimazole	1 gm
Dexamethasone acetate	44 mg
Neomycin sulphate	645 mg

## Action

Medihist combines the antimycotic/antibacterial activity of Clotrimazole with the anti-inflammatory, anti-allergic and antipruritic effect of Dexamethasone, and the antibacterial activity of neomycin in a well-tolerated cream base. Clotrimazole is a broad-spectrum antimycotic agent exerting fungicidal activity against dermatophytes such as *Trichophyton*, *Microsporum* and *Epidermophyton* species, against yeasts such as *Candida* species, against molds and other fungi, as well as against some Gram-positive bacteria such as streptococci and staphylococci.

Neomycin acts against both Gram-positive and a broad spectrum of Gram-negative bacteria such as *Escherichia coli*, *Proteus*, *Pseudomonas* and others, and is considered a classic anti-infective component in dermatological preparations. Medihist is particularly useful when a mixed fungal and/or bacterial skin infection accompanied by local **inflammation**.

## Indications

Medihist indicated for the treatment of mycotic infections of the skin complicated by inflammation and/or secondary infection. After the inflammation stage has subsided, treatment may be continued with a preparation containing an antimycotic agent alone, such as plain Clotrimazole (Candizone), without the added corticosteroid or antibiotic component.

## Contraindications

Proven intolerance or hypersensitivity to any of the individual constituents. Topical corticosteroids are contraindicated in tuberculosis of the skin, herpes simplex, vaccinia and varicella.

## Warnings

Do not use in or around the eyes.

## Pregnancy

Category B

Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

## Nursing Mothers

It is unknown whether topical application of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk.

Therefore, caution should be exercised when topical corticosteroids are applied to nursing women.

## Paediatric Use

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced Hypothalamic-pituitary-adrenal (HPA) axis suppression and Cushing's syndrome than mature patients, because of a larger skin surface area to body weight ratio. Therefore, application of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen.

## Adverse Reactions

The following local adverse reactions have been reported with topical corticosteroids: burning sensation, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, and maceration of the skin, secondary infection, striae, and skin atrophy.

Ototoxicity and nephrotoxicity have been reported with the topical use of neomycin.

### **Precautions**

In general, systemic side effects should not be expected to occur following local application of Medihist, since systemic absorption through the skin is minimal.

However, in prolonged use with high doses applied to large skin surfaces, absorption of sufficient quantities with potential systemic effects may occur.

In any cases of such prolonged use, the physician should weigh the benefits of the treatment against the possibilities of side effects such as toxicity to the kidneys or ears due to potential absorption of neomycin, or side effects such as electrolyte imbalance, gastrointestinal disturbances, hyperglycemia, myopathy, osteoporosis and hemorrhage or even reversible HPA suppression due to systemic absorption of topical corticosteroids. The usual short-term application of combined preparations such as Medihist does not normally result in side effects such as hypopigmentation, skin atrophy or striae.

Skin tolerance to Medihist is usually excellent, although specific patient sensitivity might occur. Dryness of the skin may require treatment with a suitable grease-based ointment or moisturizing cream.

### **Dosage and Administration**

Rub a sufficient quantity of Medihist into the affected skin area, after cleansing, twice daily, preferably mornings and evenings, until the cream is no longer visible. The treatment should be continued for several days after disappearance of symptoms such as itching and burning, in order to assure complete eradication of the infection.

In highly acute diseases, the cream may be applied to sterile gauze to maintain contact with the skin for as long as possible. In refractory cases where no response seen after treatment for 8-10 days, the attending physician must determine the further course of treatment.

### **Presentation**

Tube of 15 grams.