

NYSTAMETHASON (Cream)



COMPOSITION: Each 1 g NYSTAMETHASONE cream contains:

1000000 I.U Nystatin, 11.5 mg Chlorhexidine dihydrochloride, 1 mg Dexamethasone.

Excipients: Vaseline, Lanoline, Beeswax, Hard Paraffin, Liquid Paraffin, Corn Oil, Glyceryl Monostearate, Emulgin B2, Cetostearyl Alcohol.

PROPERTIES:

Nystatin acts as fungicidal by complexing with sterols of the cytoplasmic membrane and altering the cell wall of the fungus.

Chlorhexidine acts like antimicrobial by adsorption of the cationic part to the cell wall of the microorganisms. The resulting change in the permeability of the cell wall results in the leakage of intracellular substances or the penetration of Chlorhexidine into the cytoplasm.

Dexamethasone is a synthetic, medium-strong glucocorticoid. That is results in anti-inflammatory, anti-allergic, itching-stopping, immunosuppressive and anti-proliferative effects.

PHARMACOKINETICS:

Nystatin and chlorhexidine are absorbed when applied locally through the intact skin and mucous membrane occurs at low levels. Accurate data on absorption and pharmacokinetics are not available. The penetration and Permeation of dexamethasone depends on the localization, the skin condition, the age and the mode of application. Under normal conditions, only a fraction of the locally applied dose is systemically available.

INDICATIONS:

Microbial (by Candida or bacteria) superimposed or infected skin diseases such as: soreness (intertrigo, intertriginous Eczema), balanitis, balanoposthitis, Analekzem, Perianalekzem, Pruritus vulvae, Perlèches, microbial eczema, seborrheic Eczema.

Before the start of the therapy, a safe detection of Candida (culture) is to be carried out.

CONTRAINDICATIONS:

- Hypersensitivity to the active substances or to any of the excipients.
- Specific skin processes (syphilis, tuberculosis), chickenpox (varicella), vaccination reactions, rosacea, perioral dermatitis.

WARNINGS AND PRECAUTIONS:

- The application to the eye and the ear should be avoided.
- This cream should not be applied to open wounds.
- Large-scale and long-term treatments generally require special care. A continuous application time of 2-3 weeks should not be exceeded whenever possible.
- Very strong, strong and medium-potent corticosteroids should be used on the face and in the genital area with caution and not longer than 1 week.
- Corticosteroids may mask symptoms of an allergic skin reaction to any component of the preparation.
- If no improvement occurs within a few days, the diagnosis should be reviewed. Superinfection with resistant bacteria or hypersensitivity to any component of the preparation could be the cause.

Pregnancy:

This drug is contraindicated during pregnancy.

Breastfeeding:

No data are available on the use of this drug during lactation. Dexamethasone passes through the placenta and can pass into the mother's milk after topical application. This drug should therefore not be used in breastfeeding mothers.

DRUG INTERACTIONS:

In combination with antibiotics, nystatin can influence their effects synergistically (oxytetracycline) or antagonist (chloramphenicol).

Incompatibilities:

Chlorhexidine can be inactivated by soaps.

Nystatin is inactivated by magnesium and calcium ions, fatty acids, cysteine, Glutathione, sodium thioglycolate, glucose, maltose, lactose, phosphate buffer and serum.

SIDE EFFECTS:

It is usually well tolerated on skin and mucous membrane. If the condition worsens, the treatment should be discontinued and the physician should be consulted.

Occasionally: Irritation of the skin, burning, redness, pruritus.

Rare: Local hypersensitivity reactions.

DOSAGE AND ADMINISTRATION:

Apply 2 to 3 times daily to the skin and mucous membranes. The duration of application should not be longer than 10 days.

OVERDOSE:

Not relevant for nystatin and chlorhexidine, since both are not practically absorbed. Dexamethasone is only slightly absorbed compared to other corticoids, local or systemic side effects occur only after extensive and long-lasting therapy. Symptoms are those of a corticosteroid overdose, antidote is discontinuation of the preparation.

STORAGE CONDITIONS:

- Store at room temperature, between (15 - 30) °C.
- Keep out of reach of children.

PACKAGING: Aluminum tube contains 20 g NYSTAMETHASONE cream/carton box.

*** THIS IS A MEDICAMENT ***

- Keep out of reach of children.
- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly doctor's prescriptions, the method of use and instructions of the pharmacist who sold the medicament.
- The doctor and pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

(Council of Arab Ministers)

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