NYADERM Preparations

(Nystatin)

Antifungal Antibiotic

Indications: ***Cream and Ointment***: *Treatment of cutaneous or mucocutaneous mycotic infections caused by Candida (Monilia) albicans.*

Vaginal Cream: *Local treatment of vaginal infections caused by Candida (Monilia) albicans and other Candida species.*

Oral Suspension: *Prevention and treatment of candidal infections of the oral cavity and esophagus, for intestinal candidiasis and for protection against candidal overgrowth during antimicrobial or corticosteroid therapy. The suspension is particularly useful in the treatment of thrush in the newborn and provides effective prophylaxis against oral candidiasis (thrush) in newborn infants with positive cultures and in infants born of mothers with positive vaginal cultures.*

Contraindications: *Hypersensitivity to nystatin or any components of Nyaderm products.*

Precautions: *Nystatin exhibits no appreciable activity against bacteria, protozoa or viruses. Discontinue medication if irritation occurs from topical or intravaginal use or no symptomatic response is noted. Not recommended for ophthalmic use; use cautiously on lesions close to the eye. Occlusive dressings should be avoided.*

Pregnancy and Lactation: Safety of nystatin preparations has not been established during pregnancy. Therefore, they should be used cautiously on pregnant patients and should not be used during lactation.
Appropriate measures should be taken to avoid possible reinfection during sexual intercourse.

Adverse Effects: *Large oral doses have occasionally produced diarrhea, gastrointestinal distress, nausea and vomiting. Local or intravaginal irritation occurs rarely.*

Dosage: ***Topical Cream and Ointment***: *Apply liberally to affected area 1 to 4 times daily until healing is complete or as prescribed by the physician. Continue medicine for full course of treatment. For external use only.*

Vaginal Cream: *Usual dosage is 4 g (100,000 units) 1 or 2 times daily deposited high in the vagina by means of the applicator. In most cases 2 weeks of therapy will be sufficient, but more prolonged treatment may be necessary. Administration should generally be continued for at least 48 hours after clinical cure to prevent relapse.*

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Oral Suspension: *Infants: The usual prophylactic and therapeutic dosage is 1 mL (100,000 units) four times daily, dropped into the side of the mouth and swallowed. Dosage may be increased if necessary. When given concomitantly with an oral antibacterial agent, the suspension should be continued at least as long as the antibacterial agent. Therapeutic administration should generally be continued for at least 48 hours after clinical cure to prevent relapse. For prophylaxis in the newborn, the suggested dosage regimen is 1 mL once daily by dropper directly into the mouth.*
Children and Adults: The usual therapeutic dose is 1 mL (100,000 units) four times daily dropped into the mouth and held for some time before swallowing. Treatment should be continued for at least 48 hours following clinical cure to prevent relapse. Dosage may be doubled, if necessary, for those occasional infections which are severe or difficult to treat.
Note: When candidal lesions of the skin and/or nasal, vaginal or rectal mucosae are present in addition to intestinal infection, these should be treated concomitantly with a topical anticandidal preparation.

Supplied: ***Cream:*** *Each g contains nystatin USP 100,000 units in an aqueous, perfumed vanishing cream base compounded with aluminum hydroxide gel, titanium dioxide, propylene glycol, sorbitol solution, white petrolatum, polyoxyethylene fatty alcohol ether, silicon fluid, glyceryl monostearate pure, polyethylene glycol-400 monostearate, perfume, purified water, methylparaben, propylparaben and sodium hydroxide to adjust the pH. Tubes of 15 and 30 g and jars of 454 g.*
Ointment: *Each g contains nystatin USP 100,000 units in a soft ointment base compounded with white petrolatum, fractionated coconut oil, methylparaben and propylparaben. Tubes of 15 and 30 g and jars of 400 g.*
Vaginal Cream ^{Pr}*: Each g contains nystatin USP 25,000 units in a cream base compounded with propylene glycol, aluminum hydroxide gel, polyoxyethylene fatty acid ether, white petrolatum, purified water, methylparaben, propylparaben, silicon fluid and sodium hydroxide or hydrochloric acid to adjust the pH. Tubes of 120 g with applicator designed to deliver a 4 g dose (100,000 units).*
Oral Suspension ^{Pr}*: Each mL of pale yellow, cherry-mint flavoured suspension contains nystatin USP 100,000 units. Tartrazine-free. Bottles of 24 and 48 mL with a calibrated dropper.*

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