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Nystatin

Updated: February 7, 2014.

OVERVIEW

Introduction

Nystatin is a topical and oral antifungal agent with activity against many species of yeast and candida albicans, which is used largely to treat skin and oropharyngeal candidiasis. Nystatin is not absorbed orally and has not been linked to drug induced liver injury.

Background

Nystatin (nye stat' in) is a polyene macrolide antibiotic that acts by binding to sterols in the plasma membranes of fungi causing the cells to leak, eventually leading to fungal cell death. Nystatin is indicated for the treatment of yeast and candidal infections of the skin, mucous membranes and gastrointestinal tract. It is not absorbed orally and thus not indicated for invasive fungal infections. Nystatin was approved by the FDA in 1971 and is currently widely used in the treatment of superficial yeast infections and candida infections of the skin, mucous membranes and gastrointestinal tract, including oropharyngeal candidiasis. Nystatin is available in multiple forms such as tablets, troches, powder for suspension, creams and ointments and varying concentrations which are usually measured in units. Nystatin is available in generic forms and under brand names such as Mycostatin, Nilstat, Nystat and Nystop. The recommended dose for oropharyngeal candidiasis is 500,000 to 1,000,000 units 3 to 5 times daily as oral suspension or tablets (dissolved in the mouth) for 1 to 2 weeks. Common side effects include metallic taste, dry mouth, anorexia and nausea.

Hepatotoxicity

Nystatin therapy has been associated with a low rate of serum enzyme abnormalities, although it has been difficult to attribute these elevations to nystatin. Despite its use for several decades, there have been no convincing cases of acute hepatic injury linked to nystatin therapy. While nystatin is usually is not normally absorbed, low concentrations may enter the circulation in patients with inflammation and damage to the gastrointestinal tract. Nevertheless, nystatin is considered very safe and is unlikely to cause hepatic injury.

Mechanism of Injury

The absence of hepatotoxicity from nystatin is probably largely due to lack of absorption.

Drug Class: Antifungal Agents

PRODUCT INFORMATION

REPRESENTATIVE TRADE NAMES

Nystatin – Generic, Mycostatin®, Nystat®

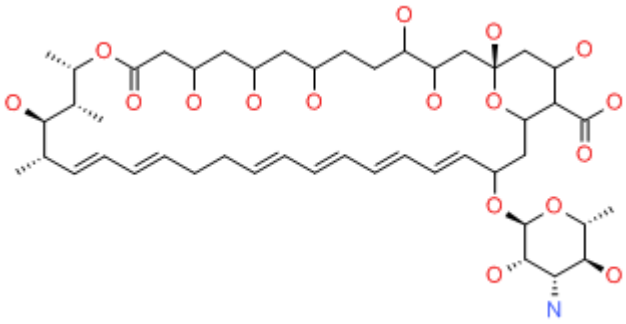
DRUG CLASS

Antifungal Agents

COMPLETE LABELING

Product labeling at DailyMed, National Library of Medicine, NIH

CHEMICAL FORMULA AND STRUCTURE

DRUG	CAS REGISTRY NUMBER	MOLECULAR FORMULA	STRUCTURE
Nystatin	1400-61-9	C46-H83-N-O18 C47-H75-N-O17	

ANNOTATED BIBLIOGRAPHY

References updated: 07 February 2014

Zimmerman HJ. Antifungal agents. In, Zimmerman HJ. Hepatotoxicity: the adverse effects of drugs and other chemicals on the liver. 2nd ed. Philadelphia: Lippincott, 1999, pp. 609-11.

(Expert review of hepatotoxicity of antifungal agents published in 1999; nystatin is considered safe because it is not absorbed).

Moseley RH. Antifungal agents. Antibacterial and antifungal agents. In, Kaplowitz N, DeLeve LD, eds. Drug-induced liver disease. 3rd ed. Amsterdam: Elsevier, 2013, pp. 470-81.

(Review of hepatotoxicity of antifungal agents does not discuss nystatin).

Bennett JE. Antimicrobial agents: antifungal agents. In, Brunton LL, Chabner BA, Knollman BC, eds. Goodman & Gilman's the pharmacological basis of therapeutics. 12th ed. New York: McGraw-Hill, 2011, pp. 1571-92.

(Textbook of pharmacology and therapeutics).

Pons V, Greenspan D, Lozada-Nur F, McPhail L, Gallant JE, Tunkel A, Johnson CC, et al. Oropharyngeal candidiasis in patients with AIDS: randomized comparison of fluconazole versus nystatin oral suspensions. Clin Infect Dis 1997; 24: 1204-7. PubMed PMID: 9195083.

(Controlled trial of 2 weeks of nystatin vs fluconazole in 167 patients with HIV infection and oropharyngeal candidiasis; side effects were minimal and included liver enzyme elevations in 2 subjects on fluconazole, but none on nystatin).

Pons V, Greenspan D, Debruin M. Therapy for oropharyngeal candidiasis in HIV-infected patients: a randomized, prospective multicenter study of oral fluconazole versus clotrimazole troches. The Multicenter Study Group. J Acquir Immune Defic Syndr 1993; 6: 1311-6. PubMed PMID: 8254467.

(Trial of 14 days of fluconazole vs clotrimazole in 334 HIV infected patients with oropharyngeal candidiasis; 2 patients on fluconazole but none of clotrimazole were withdrawn for serum ALT elevations).

Flynn PM, Cunningham CK, Kerkering T, San Jorge AR, Peters VB, Pitel PA, Harris J, et al. Oropharyngeal candidiasis in immunocompromised children: a randomized, multicenter study of orally administered fluconazole suspension versus nystatin. The Multicenter Fluconazole Study Group. J Pediatr 1995; 127: 322-8. PubMed PMID: 7636666.

(Controlled trial of 14 days of fluconazole vs nystatin in 182 children with oropharyngeal candidiasis; liver test abnormalities occurred in 8% on nystatin vs 7% on fluconazole; no early discontinuations because of abnormalities).

Young GA, Bosly A, Gibbs DL, Durrant S. A double-blind comparison of fluconazole and nystatin in the prevention of candidiasis in patients with leukaemia. Antifungal Prophylaxis Study Group. Eur J Cancer 1999; 35: 1208-13. PubMed PMID: 10615231.

(Controlled trial of nystatin vs fluconazole for prevention of fungal infections in 160 patients with leukemia on chemotherapy; ALT elevations occurred in 24% of nystatin vs 24% of fluconazole treated patients, but most were attributed to other causes; one patient in each group developed "hepatitis").

Antifungal drugs. Treat Guidel Med Lett 2009; 7: 95-102. PubMed PMID: 19940816.

(Concise summary of therapy of fungal infections with recommendations on agents, dosage and duration of treatment and safety; nystatin is listed as a topical antifungal agent, but is not discussed).

Pienaar ED, Young T, Holmes H. Interventions for the prevention and management of oropharyngeal candidiasis associated with HIV infection in adults and children. Cochrane Database Syst Rev 2010; 11: CD003940. PubMed PMID: 16856025.

(Metaanalysis of trials comparing different regimens of therapy for orophyaryngeal candidiasis; does not discuss hepatotoxicity).