Pediatric Use
Safety and effectiveness have been established in the pediatric population from birth to 16 years.
(See DOSAGE AND ADMINISTRATION.)

Geriatric Use
Clinical studies with nystatin cream did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

ADVERSE REACTIONS
The frequency of adverse events reported in patients using nystatin cream is less than 0.1%. The more common events that were reported include allergic reactions, burning, itching, rash, eczema, and pain on application.
(See PRECAUTIONS: General.)

DOSAGE AND ADMINISTRATION
Adults and Pediatric Patients (Neonates and Older):
Apply liberally to affected areas twice daily or as indicated until healing is complete.

HOW SUPPLIED
Nystatin cream: 100,000 units nystatin per gram in an aqueous, vanishing cream base, in 15 g, 30 g, and 60 g tubes.

STORAGE
Store at room temperature, avoid freezing.

Manufactured for:
QUALITEST PHARMACEUTICALS
Huntsville, AL 35811

NYSTATIN CREAM, USP
Rx only
FOR TOPICAL USE ONLY • NOT FOR OPHTHALMIC USE

DESCRIPTION
Nystatin is a polyene antifungal antibiotic obtained from Streptomyces nursei.

Structural formula:

Nystatin cream is for dermatologic use.

Nystatin cream for topical use, contains 100,000 USP nystatin units per gram. Inactive ingredients: aluminum hydroxide compressed wet gel, ceteryl alcohol (and) ceteth-20, glyceryl monostearate, polyoxy 40 stearate, propylene glycol, purified water, simethicone, sorbic acid, sorbitol solution, titanium dioxide, and white petrolatum.

CLINICAL PHARMACOLOGY
Pharmacokinetics
Nystatin is not absorbed from intact skin or mucous membrane.

Microbiology
Nystatin is an antibiotic which is both fungistatic and fungicidal in vitro against a wide variety of yeasts and yeast-like fungi, including Candida albicans, C. parapsilosis, C. tropicalis, C. guilliermondii, C. pseudotropicalis, C. krusei, Torulopsis glabrata, Tricophyton rubrum, T. mentagrophytes.
Nystatin acts by binding to sterols in the cell membrane of susceptible species resulting in a change in membrane permeability and the subsequent leakage of intracellular components. On repeated subculturing with increasing levels of nystatin, Candida albicans does not develop resistance to nystatin. Generally, resistance to nystatin does not develop during therapy. However, other species of Candida (C. tropicalis, C. guilliermondii, C. krusei, and C. stellatooides) become quite resistant on treatment with nystatin and simultaneously become cross resistant to amphotericin as well. This resistance is lost when the antibiotic is removed.

Nystatin exhibits no appreciable activity against bacteria, protozoa, or viruses.

INDICATIONS AND USAGE
Nystatin cream is indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by Candida albicans and other susceptible Candida species.

This cream is not indicated for systemic, oral, intravaginal or ophthalmic use.

CONTRAINDICATIONS
Nystatin cream is contraindicated in patients with a history of hypersensitivity to any of its components.

PRECAUTIONS
General
Nystatin cream should not be used for the treatment of systemic, oral, intravaginal or ophthalmic infections.

If irritation or sensitization develops, treatment should be discontinued and appropriate measures taken as indicated. It is recommended that KOH smears, cultures, or other diagnostic methods be used to confirm the diagnosis of cutaneous or mucocutaneous candidiasis and to rule out infection caused by other pathogens.

INFORMATION FOR THE PATIENT
Patients using this medication should receive the following information and instructions:

1. The patient should be instructed to use this medication as directed (including the replacement of missed doses). This medication is not for any disorder other than that for which it is prescribed.

2. Even if symptomatic relief occurs within the first few days of treatment, the patient should be advised not to interrupt or discontinue therapy until the prescribed course of treatment is completed.

3. If symptoms of irritation develop, the patient should be advised to notify the physician promptly.

Laboratory Tests
If there is a lack of therapeutic response, KOH smears, cultures, or other diagnostic methods should be repeated.

Carcinogenesis, Mutagenesis, Impairment of Fertility
No long-term animal studies have been performed to evaluate the carcinogenic potential of nystatin. No studies have been performed to determine the mutagenicity of nystatin or the effects on male or female fertility.

Pregnancy: Teratogenic Effects
Category C. Animal reproduction studies have not been conducted with any nystatin cream. It also is not known whether this cream can cause fetal harm when used by a pregnant woman or can affect reproductive capacity. Nystatin cream should be prescribed for a pregnant woman only if the potential benefit to the mother outweighs the potential risk to the fetus.

Nursing Mothers
It is not known whether nystatin is excreted in human milk. Caution should be exercised when nystatin is prescribed for a nursing woman.