

## New Zealand Data Sheet

# MYCOSTATIN

*Nystatin cream*

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## NAME OF MEDICINE

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Mycostatin (Nystatin)

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## PRESENTATION

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Cream, 100,000 units/g: 15 g.

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## USES

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### **Actions**

Nystatin is a polyene antifungal antibiotic obtained from *Streptomyces noursei*.

### **Microbiology**

Nystatin is an antibiotic which is both fungistatic and fungicidal *in vitro* against a wide variety of yeasts and yeast-like fungi. Nystatin acts by binding to sterols in the cell membrane of susceptible *Candida* 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. Nystatin exhibits no activity against bacteria, protozoa or viruses.

### **Pharmacokinetics**

Nystatin is not absorbed from intact skin or mucous membranes.

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## INDICATIONS

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Nystatin topical preparations are indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida* species.

This preparation is not indicated for systemic use.

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## **DOSAGE AND ADMINISTRATION**

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Apply liberally to affected areas twice daily or as indicated until healing is complete.

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## **CONTRAINDICATIONS**

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Known sensitivity to nystatin or other components.

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## **WARNING AND PRECAUTIONS**

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Should a reaction of hypersensitivity occur, the drug should be immediately withdrawn and appropriate measures taken. Nystatin topical preparations should not be used for the treatment of systemic or ophthalmic infections.

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 these medications should receive the following information and instructions:

1. The patient should be instructed to use the medication as directed (including the replacement of missed doses). The medication is not for any disorder other than that for which it was prescribed.
2. Even if symptomatic relief occurs within the first few days of treatment, the patient should be advised not to interrupt or discontinue the medication 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 Test***

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 its effect on male or female fertility.

### ***Use in Pregnancy (Category A)***

Animal reproduction studies have not been conducted with nystatin topical preparations. It is also not known whether these preparations can cause foetal harm when used by a pregnant woman or can affect reproductive capacity. Nystatin topical preparations should be prescribed for a pregnant woman only if the potential benefit to the mother outweighs the potential risk to the foetus.

### ***Use in Lactation***

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

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## **ADVERSE EFFECTS**

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Well tolerated by all age groups including debilitated infants, even on prolonged administration. Local irritation and sensitisation (including: rash, dermatitis, pruritus and burning) have been reported. If irritation on topical application should occur, discontinue medication.

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## **PHARMACEUTICAL PRECAUTIONS**

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Shelf-life: 24 months

Storage Conditions: Store at or below 25°C.

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## **Medicine Classification**

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Pharmacy Only Medicine

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## **Package Quantities**

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1 x 15 g tube (100,000 units/g)

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## **NAME AND ADDRESS**

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Mangere  
AUCKLAND

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## **DATE OF PREPARATION**

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18 November 2009