

## **PRODUCT INFORMATION**

### **MYCOSTATIN TOPICAL (nystatin)**

#### **DESCRIPTION**

Mycostatin (nystatin). Cream is for topical use and is yellow to light yellow in colour. Mycostatin (nystatin). Cream contains Nystatin Aluminium hydroxide, Soft White Paraffin, Perfume E, Promulgen D, Propylene glycol., Simethicone, Sorbitol solution, Titanium dioxide and Water (purified).

#### **ACTIONS**

Probably alters the membrane permeability of the fungal cell allowing leakage of intracellular components.

#### **INDICATIONS**

Treatment of cutaneous mycotic infections caused by *Candida sp.*

#### **CONTRAINDICATIONS**

Known sensitivity to nystatin or other components.

#### **PRECAUTIONS**

Should a reaction of hypersensitivity occur, the drug should be immediately withdrawn and appropriate measures taken.

Mycostatin topical preparations should not be used for the treatment of systemic or ophthalmic infections.

If irritation or sensitization develops, treatment should be discontinued.

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.

#### **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 its effect on male or female fertility.

### **Use in pregnancy. (Category A)**

Animal reproduction studies have not been conducted with nystatin topical preparation. It is also not known whether these preparations can cause fetal 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 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.

## **ADVERSE REACTIONS**

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

## **DIRECTIONS FOR USE**

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

## **PRESENTATION**

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

## **POISONS SCHEDULE**

S3.

## **SPONSOR**

Aspen Pharma Pty Ltd  
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