

# AUSTRALIAN PRODUCT INFORMATION – MYCOSTATIN (NYSTATIN) ORAL DROPS SUSPENSION

## 1 NAME OF THE MEDICINE

Nystatin.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of Mycostatin Oral Drops contains 100,000 IU nystatin.

Excipients with known effect: methyl hydroxybenzoate, propyl hydroxybenzoate and sucrose.

For the full list of excipients, see Section 6.1 List of excipients.

## 3 PHARMACEUTICAL FORM

Mycostatin Oral Drops is a bright yellow suspension with characteristic cherry-like odour and flavour.

## 4 CLINICAL PARTICULARS

### 4.1 THERAPEUTIC INDICATIONS

Treatment of candidal infections of the oral cavity caused by *Candida albicans*.

### 4.2 DOSE AND METHOD OF ADMINISTRATION

Shake well before use.

**DOSAGE: Children and adults:** 1 mL four times daily. The drops should be held in the mouth and swirled around for as long as possible before swallowing. Treatment should be continued for at least 48 hours after symptoms have disappeared and cultures are returned to normal.

If signs and symptoms worsen or persist (beyond 14 days of treatment), the patient should be re-evaluated, and alternate therapy considered.

### 4.3 CONTRAINDICATIONS

Known hypersensitivity to nystatin or any of the other ingredients in the formulation (See Section 6.1 List of excipients).

### 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Mycostatin Oral Drops should not be used for the treatment of systemic mycoses.

If irritation or sensitization develops, treatment should be discontinued.

If there is a lack of therapeutic response, appropriate microbiological studies (e.g. KOH smear and/or cultures) should be repeated to confirm diagnosis of candidiasis and rule out other pathogens before instituting another course of therapy.

#### Use in the elderly

No data available.

### **Paediatric use**

No data available.

### **Effects on laboratory tests**

No data available.

### **Use in immunocompromised patients**

Higher doses, for example 500,000 units 4 times daily, may be needed. However, the use of alternate antibiotics is preferred for the treatment of oral thrush in patients with immunosuppression.

## **4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS**

Nystatin is not known to interact with other medicines.

## **4.6 FERTILITY, PREGNANCY AND LACTATION**

### **Effects on fertility**

No data available.

### **Use in pregnancy – Pregnancy Category A**

Animal reproduction studies have not been conducted with Mycostatin Oral Drops . It is also not known whether Mycostatin Oral Drops can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Mycostatin Oral Drops should be prescribed for a pregnant woman only if the potential benefit to the mother outweighs the potential risk to the fetus.

### **Use in lactation**

It is not known whether nystatin is excreted in human milk. Though gastrointestinal absorption is insignificant, caution should be exercised when nystatin is prescribed for a nursing woman.

## **4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES**

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

## **4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)**

### **Reporting suspected adverse effects**

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

Mycostatin Oral Drops is well tolerated by all age groups, even with prolonged administration. Large doses have occasionally produced diarrhoea, gastrointestinal distress, nausea and vomiting. Rash, including urticaria, has been reported rarely. Stevens-Johnson syndrome has been reported very rarely. Hypersensitivity and angioedema, including facial oedema, have been reported.

## 4.9 OVERDOSE

Oral doses of nystatin in excess of 5 million units daily have caused nausea and gastrointestinal upset.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 PHARMACODYNAMIC PROPERTIES

#### Mechanism of action

Nystatin is an antifungal antibiotic, active against yeasts and yeast like fungi, including *Candida albicans*. The antifungal activity is probably due to the binding of sterols in the cell membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components.

#### Clinical trials

No data available.

### 5.2 PHARMACOKINETIC PROPERTIES

#### Absorption

Nystatin is poorly absorbed from the gastrointestinal tract after oral administration. It is not absorbed through the skin or mucous membrane when applied topically.

### 5.3 PRECLINICAL SAFETY DATA

#### Genotoxicity

No data available.

#### Carcinogenicity

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.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 LIST OF EXCIPIENTS

Bentonite, Cherry flavour F-1242, hydrochloric acid, methyl hydroxybenzoate, polysorbate 80, propyl hydroxybenzoate, quinoline yellow, sodium calcium edetate, sucrose, and purified water.

### 6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

### 6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

#### 6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C.

#### 6.5 NATURE AND CONTENTS OF CONTAINER

24 mL glass bottle.

#### 6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

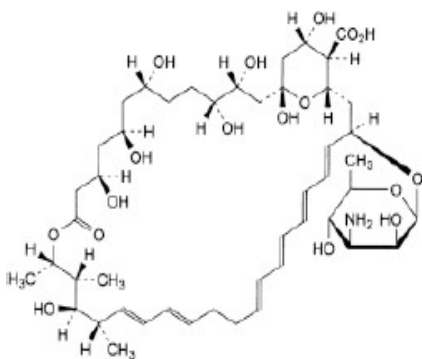
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

#### 6.7 PHYSICOCHEMICAL PROPERTIES

Nystatin is an antifungal substance obtained by fermentation using certain strains of *Streptomyces noursei* as the production micro-organism. It contains mainly tetraenes, the principal component being nystatin A1.

Nystatin is a yellow or slightly brownish powder, hygroscopic. Practically insoluble in water. Freely soluble in dimethylformamide and in dimethyl sulfoxide. Slightly soluble in methanol. Practically insoluble in alcohol. Molecular formula: C<sub>47</sub>H<sub>75</sub>NO<sub>17</sub>.

#### Chemical structure



#### CAS number

1400-61-9

### 7 MEDICINE SCHEDULE (POISONS STANDARD)

S3 – Pharmacist Only Medicine.

### 8 SPONSOR

Aspen Pharmacare Australia Pty Ltd  
34-36 Chandos Street,  
St. Leonards NSW 2065  
Australia

[www.aspenpharma.com.au](http://www.aspenpharma.com.au)

## 9 DATE OF FIRST APPROVAL

7 September 2012

## 10 DATE OF REVISION

14 September 2023

### SUMMARY TABLE OF CHANGES

<b>Section Changed</b>	<b>Summary of new information</b>
All	Updated to the new Australian Product Information format.
8	Updated sponsor details.