AUSTRALIAN PRODUCT INFORMATION

Nilstat oral drops (nystatin) suspension

1 NAME OF THE MEDICINE

Nystatin.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

List of 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

Nilstat Oral Drops [AUST R 48569] is a bright yellow, cherry flavoured suspension.

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. Continue treatment for 48 hours after symptoms have subsided.

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

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

Use in the elderly
No data available.

Paediatric use
No data available.

Effects on laboratory tests
No data available.

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 – category A
Animal reproduction studies have not been conducted with Nilstat Oral Drops suspension. It is also not known whether Nilstat Oral Drops suspension can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Nilstat Oral Drops suspension 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.

Nilstat Oral Drops suspension 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, sodium calcium edetate, sucrose, methyl hydroxybenzoate, propyl hydroxybenzoate, polysorbate 80, cherry flavour F-1242, quinoline yellow 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

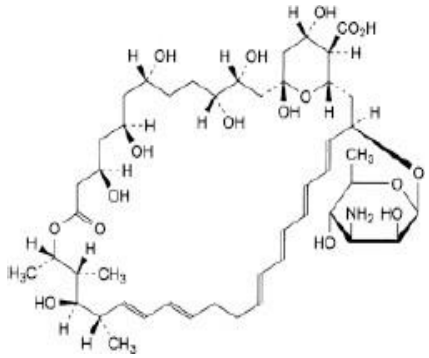
In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

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: $C_{47}H_{75}NO_{17}$.

Chemical structure



CAS number

1400-61-9

7 MEDICINE SCHEDULE (POISONS STANDARD)

S3 – PHARMACIST ONLY MEDICINE.

8 SPONSOR

Aspen Pharma Pty Ltd
34-36 Chandos St
St Leonards NSW 2065
Australia

http://www.aspenpharma.com.au

9 DATE OF FIRST APPROVAL

18/04/1994

10 DATE OF REVISION

27/8/2021

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Updated to the revised Australian product information format and content. Minor corrections to punctuation and spelling.
8	Addition of Aspen website.
