

AUSTRALIAN PRODUCT INFORMATION – NILSTAT (NYSTATIN) VAGINAL CREAM

1 NAME OF THE MEDICINE

Nystatin.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 g of Nilstat vaginal cream contains 100,000 I.U. nystatin as the active ingredient.

Excipient with known effect: sorbic acid.

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

3 PHARMACEUTICAL FORM

A smooth, uniform light-yellow cream, free from gritty particles and foreign matter.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Local treatment of vulvovaginal candidiasis.

4.2 DOSE AND METHOD OF ADMINISTRATION

The usual dosage is one full applicator of cream (5 g) to be inserted high in the vagina, once or twice daily.

Inside each package of cream is an instruction leaflet for the patient. An applicator is provided with the cream.

In most cases, two weeks of therapy will be sufficient, but more prolonged treatment may be necessary. It is important that therapy be continued during menstruation. Adjunctive measures such as therapeutic douches are unnecessary and sometimes inadvisable. Cleansing douches may be used by nonpregnant women, if desired for aesthetic purposes.

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

If irritation or sensitization develops, treatment should be discontinued.

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 – Pregnancy Category A

Animal reproduction studies have not been conducted with Nilstat vaginal cream. It is also not known whether Nilstat vaginal cream can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Nilstat vaginal cream 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)

Nystatin is virtually nontoxic, nonsensitising and is well tolerated by all age groups, even on prolonged topical administration. If irritation during intravaginal use should occur, discontinue the medication.

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.

4.9 OVERDOSE

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

Emulsifying wax, glycerol, isopropyl myristate, lactic acid, sodium hydroxide, sorbic acid, 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

Nilstat vaginal cream is available in collapsible aluminium tubes containing 15 g or 75 g cream. The tubes are capped with a plastic cap. Each tube is packed with a reusable applicator and a patient-instruction leaflet.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

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

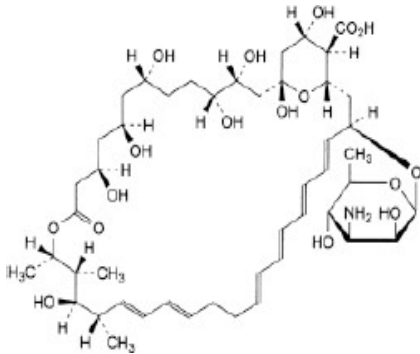
6.7 PHYSICOCHEMICAL PROPERTIES

Nystatin is an antifungal antibiotic produced by a strain of *Streptomyces noursei*. Nystatin is useful in the treatment of infections caused by *Candida (Monilia) albicans*. Nystatin has no appreciable activity against bacteria.

No detectable blood levels are obtained following topical or vaginal applications.

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: C₄₇H₇₅NO₁₇.

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 Street
St Leonards NSW 2065
Australia

www.aspenpharmacare.com.au

9 DATE OF FIRST APPROVAL

9 September 1991

10 DATE OF REVISION

11 April 2023

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	Updated to the new Australian Product Information format.