New Zealand Data Sheet

1. PRODUCT NAME

NILSTAT capsule, 500,000 IU

NILSTAT tablet, 500,000 IU

NILSTAT vaginal cream, 100,000 U/5 g

NILSTAT Drops Oral drops, 100,000 IU/mL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Nystatin - 500,000 IU per tablet

Nystatin - 500,000 IU per capsule

Nystatin - 100,000 U per 5 g vaginal cream

Nystatin - 100,000 IU per 1 mL oral drops

3. PHARMACEUTICAL FORM

NILSTAT capsules:

Buff coloured, hard shell capsules with the inscription 'Nilstat'. Each capsule contains 500,000 units of nystatin.

NILSTAT tablets:

Round, buff (deep yellow) tablets each containing 500,000 units of nystatin.

NILSTAT vaginal cream:

Each gram of cream contains 20,000 units of nystatin in a water miscible base.

NILSTAT Drops oral drops:

Each mL contains 100,000 units of nystatin in a sucrose suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nystatin is indicated for the treatment of cutaneous, mucocutaneous, oral, intestinal and vulvovaginal infections caused by *Candida albicans*.

Tablets and capsules: Intestinal candidiasis.

Vaginal cream: Local treatment of vulvovaginal candidiasis.

Oral drops: Infections of the oral cavity caused by *Candida albicans*.

4.2 Dose and method of administration

Capsules and tablets: Usual dosage - 500,000 to 1 million units (1 to 2 tablets or capsules) three times daily. Treatment should generally be continued for at least 48 hours after clinical cure to prevent a relapse.

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

Oral drops: Infants, children and adults - 1 mL (100,000 units) four times daily.

The dose should be administered under the tongue or in the buccal cavity and held in the mouth and swirled around as long as possible before swallowing.

4.3 Contraindications

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

Oral drops

Nilstat 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.

Vaginal Cream

While NILSTAT vaginal cream has only minimal effect on the tensile properties of latex rubber condoms, patients should be aware of the risk that condoms and diaphragms may be weakened when used with NILSTAT vaginal cream. Therefore, the use of contraceptive diaphragms and condoms with NILSTAT vaginal cream is not recommended.

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.

4.5 Interaction with other medicines and other forms of interaction

No data available.

4.6 Fertility, pregnancy and lactation

Fertility

No data available.

Pregnancy

Category A

Systemic absorption of nystatin is negligible after topical, vaginal, or oral administration. However, as with all medicines, caution should be exercised when nystatin is administered to pregnant women.

Lactation

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

4.7 Effects on ability to drive and use machines

No data available.

4.8 Undesirable effects

Nystatin is well tolerated by all age groups even with prolonged administration. If irritation or sensitization develops, treatment should be discontinued. Nausea has been reported occasionally during therapy.

Large oral doses have occasionally produced diarrhoea, gastrointestinal distress, nausea and vomiting.

Rash, including urticaria, has been reported rarely. Steven-Johnson Syndrome has been reported very rarely. Hypersensitivity and angioedema, including facial edema have been reported.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

Since the absorption of nystatin from the gastro-intestinal tract is negligible, overdosage or accidental ingestion causes no systemic toxicity. Oral doses of nystatin in excess of 5 million units daily have caused nausea and gastrointestinal upset.

Symptomatology as described in the UNDESIRABLE EFFECTS section would be expected. There are no specific guidelines relating to the treatment of overdosage with NILSTAT.

For risk assessment and advice on the management of overdose please contact

the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic preoperties

Nystatin is an antifungal antibiotic, produced by a strain of Streptomyces noursei, 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. Nystatin has no appreciable activity against bacteria.

5.2 Pharmacokinetic properties

Nystatin is absorbed very sparingly following oral administration when given in the recommended doses. The minimal absorption from oral dosage forms may however, be sufficient to provoke an allergic reaction in hypersensitive patients. No detectable blood levels are obtained following topical or vaginal applications.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

In addition to Nystatin, the following excipients are present in NILSTAT products:

Tablets: Lactose monohydrate, ethylcellulose, magnesium stearate, sodium starch glycolate, carnauba wax, purified water, Opadry Yellow OY-2144A (hypromellose, macrogol 400, iron oxide yellow CI 77492, titanium dioxide).

Capsules: Lactose monohydrate, magnesium stearate, ethanol, iron oxide yellow CI 77492, titanium dioxide, gelatin, isopropyl alcohol, shellac and carbon black CI 77266.

Vaginal cream: Emulsifying wax, isopropyl myristate, glycerol, sorbic acid and purified water (lactic acid or sodium hydroxide to adjust pH 4.5-5.5).

Oral Drops: Cherry flavor F1242, hydrochloric acid, methyl hydroxybenzoate, propyl hydroxybenzoate, sucrose, polysorbate 80, sodium calcium edetate (hydrate), purified water, bentonite, quinoline yellow, saponite, sodium hydroxide.

6.2 Incompatibilities

No data available.

6.3 Shelf life

Capsules: 24 months

Oral drops: 18 months

Tablets: 18 months

Vaginal cream: 24 months

6.4 Special precautions for storage

Capsules, drops, tablets and vaginal cream: Store at or below 25°C.

6.5 Nature and contents of container

Capsules: glass bottle, 50's

Oral Drops: plastic bottle, 24 mL

Tablets: glass bottle, 50's

Vaginal cream: aluminium tube, 75 g

6.6 Special precautions for disposal (and other handling)

No data available.

7. MEDICINE SCHEDULE

Prescription Medicine:

NILSTAT capsules

NILSTAT tablets

Restricted Medicine:

NILSTAT Drops oral drops

NILSTAT vaginal cream

8. SPONSOR

Pharmacy Retailing (NZ) Limited
58 Richard Pearse Drive
Airport Oaks, Auckland
New Zealand

9. DATA OF FIRST APPROVAL

3 April 2013

10. DATE OF REVISION OF THE TEXT

08 May 2026

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.	Updated subheadings
4.6	Updated information on lactation
4.8	Updated information on side effects
4.9	Updated information on overdose