

New Zealand Data Sheet

NILSTAT®

Nystatin - 500,000 I.U. capsules
Nystatin - 100,000 I.U./mL oral drops
Nystatin - 500,000 I.U. tablets
Nystatin - 20,000 I.U./g vaginal cream

Presentation

NILSTAT capsules:

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

NILSTAT oral drops:

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

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.

Uses

Actions

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.

Pharmacokinetics

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.

Indications

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

Tablets and capsules: Intestinal candidiasis.

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

Vaginal cream: Local treatment of vulvovaginal candidiasis.

Dosage and 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.

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 as long as possible before swallowing.

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.

Contraindications

Hypersensitivity to nystatin.

Warnings and Precautions

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 Pregnancy

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.

Adverse Effects

Nystatin is nontoxic, and well tolerated by all age groups even with prolonged administration. Large oral doses have occasionally produced diarrhoea, gastrointestinal distress, nausea and vomiting. There have been reports of allergic reactions to orally administered Nystatin, although these are rare.

Interactions

Nil.

Overdosage

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

Pharmaceutical Precautions

Capsules, drops, tablets and vaginal cream :

Store under 25°C.

Medicine Classification

Prescription Medicine

NILSTAT Capsules
NILSTAT Tablets

Restricted Medicine

NILSTAT Oral Drops
NILSTAT Vaginal Cream

Package Quantities

Capsules: 500,000 I.U./capsule, 50's

Drops: 100,000 I.U./mL, 24 mL

Tablets: 500,000 I.U./tablet, 50's

Vaginal cream: 20,000 I.U./g, 75 g

Further Information

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

Tablets:

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

Capsules:

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

Oral Drops:

Propyl hydroxybenzoate, sucrose, polysorbate 80, sodium calciumedetate, methyl hydroxybenzoate, water - purified, bentonite, quinoline yellow CI 47005 and cherry flavour F-1242.

Vaginal cream:

Wax-emulsifying, isopropyl myristate, glycerol, sorbic acid and water-purified (lactic acid or sodium hydroxide to adjust pH 4.5-5.5).

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