

PRESCRIBING INFORMATION

ratio-NYSTATIN

Nystatin oral suspension USP
100 000 units / mL

Nystatin oral suspension USP
100 000 units / mL
Sucrose free

Nystatin oral tablets USP
500 000 units / tablet

Nystatin Vaginal cream USP
25 000 units / g and 100 000 units / g

Nystatin vaginal tablets USP
100 000 units / tablet

Nystatin cream USP
100 000 units / g

Nystatin ointment USP
100 000 units / g

Nystatin powder USP
1 billion units / jar

Antifungal / Antibiotic

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Control #:

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INDICATIONS AND CLINICAL USE

Oral suspension:

Monilial infections of the mouth (thrush) and intestinal moniliasis in infants and children.

Oral tablets:

Prevention and treatment of intestinal moniliasis. Prevention or treatment of lower intestinal and anal infections caused by *Candida albicans* (monilia).

Vaginal cream and tablets:

Local treatment of vaginal mycotic infections caused by *Candida albicans*.

Topical cream and ointment:

For dermatological use only. Treatment of cutaneous or mucocutaneous mycotic infections caused by *Candida* (monilia) species.

Powder:

For the treatment of infections of the oral cavity caused by *C. albicans* (monilia)

PRECAUTIONS

Little activity against bacteria, protozoa and viruses. Discontinue medication if irritation should occur from topical or intravaginal use.

Pregnancy:

During pregnancy, the vaginal applicators should be used only on the advice of a physician.

Appropriate measures should be taken to avoid reinfection during sexual intercourse.

ADVERSE REACTIONS

High oral dosage may produce nausea, vomiting and diarrhea. Tachycardia, bronchospasm, facial swelling, urticaria and non-specific myalgia have been reported rarely.

DOSAGE

Therapy should generally be continued for at least 48 hours after clinical cure to prevent relapse. When oral nystatin is given concomitantly with an oral antibacterial agent, oral nystatin should be continued at least as long as the antibacterial agent. Local treatment of chronic or resistant vaginal, oral or cutaneous moniliasis with nystatin may be supplemented with oral nystatin administration.

Oral suspension: *Infants and children:* 100 000 units 3 to 4 times daily for oral (thrush) and intestinal moniliasis. For treatment of infections of the oral cavity, the medication should be dropped directly on the tongue by means of the calibrated dropper and retained in the mouth for as long as possible before swallowing. For treatment of intestinal infections, may be dropped directly on the tongue by means of the calibrated dropper, or may be mixed with milk, lukewarm formula, or other non-acid vehicles, or incorporated in honey, jelly or peanut butter.

Oral suspension (SUCROSE FREE): *Infants:* prophylactic and therapeutic: 100 000 units 4 times daily, dropped into the mouth and swallowed. *Children and adults:* 100 000 units 4 times daily, dropped into the mouth and held for some time before swallowing. Dosage may be doubled for those occasional infections which are severe or difficult to treat, if necessary.

Oral tablets: 500 000 units 3 times daily. Double dosage, if necessary, for adults.

Vaginal cream (25 000 units/g): Insert the contents of 1 applicatorful of cream (4 grams of cream) deeply into the vagina, once or more daily as directed by the physician.

Vaginal cream (100 000 units/g): 1 applicatorful (5 g of cream) daily. In cases of severe infection, repeat application every 12 hours. Generally 2 weeks of therapy will be sufficient however, more prolonged therapy may be necessary. Therapy should be continued during menstruation.

Vaginal tablets: 1 tablet inserted high in the vagina by means of the applicator once or twice daily for 2 weeks or as required. Therapy should be continued during menstruation.

Topical cream and ointment: Apply cream or ointment liberally to affected areas twice daily or as prescribed by the physician.

Powder: *Children and adults:* Oral suspension: 400 000 to 600 000 units 4 times daily.

SUPPLIED: **Oral suspension:** Each mL contains: nystatin 100 000 units. **Non-medicinal ingredients in alphabetical order:** artificial flavouring, calcium disodium EDTA, D&C yellow #10, magnesium aluminum silicate, methylparaben, polysorbate 80, propylparaben, purified water and sucrose. Energy: < 3 kcal/mL. Bottles of 24, 48 and 100 mL with calibrated dropper. Store between 15-30°C.

Oral suspension (SUCROSE FREE): Each mL contains: nystatin 100 000 units. **Non-medicinal ingredients in alphabetical order:** artificial flavouring, dibasic sodium phosphate, disodium EDTA, hydroxyethyl cellulose, monobasic potassium phosphate, potassium sorbate, propylene glycol, purified water, sodium benzoate, sodium metabisulfite, sodium saccharin, sorbitol and vanillin. Bottles of 50 and 100 mL with calibrated dropper. Store between 15-30°C.

Oral tablets: Each round, film-coated, pink tablet, engraved "LL" and "N5" contains: nystatin 500 000 units. **Non-medicinal ingredients in alphabetical order:** corn starch, D&C red #30 aluminum lake, ethylcellulose, hydroxypropyl methylcellulose, mineral oil, magnesium stearate, sodium lauryl sulfate, stearic acid and titanium dioxide. Bottles of 100. Store between 15-30°C.

Vaginal cream (25 000 units/g): Each g contains: nystatin 25 000 units. **Non-medicinal ingredients in alphabetical order:** methylparaben, polyethylene glycol,

purified water and sorbitan monostearate. Tubes of 120 g with re-usable applicator. Store between 15-30°C.

Vaginal cream (100 000 units/g): Each g contains: nystatin 100 000 units. **Non-medicinal ingredients in alphabetical order:** emulsifying wax, glycerin, isopropyl myristate, purified water and sorbic acid. Tubes of 75 g with re-usable applicator. Store between 15-30°C.

Vaginal tablets: Each oval, pale yellow tablet, engraved "LL" and "N6", contains: nystatin 100 000 units. **Non-medicinal ingredients in alphabetical order:** corn starch, lactose, magnesium stearate, povidone and sorbitol. Boxes of 15 with applicator. Store between 15-30°C.

Topical cream: Each g contains: nystatin 100 000 units. **Non-medicinal ingredients in alphabetical order:** emulsifying wax, glycerin, isopropyl myristate, purified water and sorbic acid. Tubes of 15 and 30 g. Jars of 450 g. Store between 15-30°C.

Topical ointment: Each g contains: nystatin 100 000 units. **Non-medicinal ingredients in alphabetical order:** mineral oil and polyethylene. Tubes of 30 g. Store between 15-30°C.

Powder: For use only in extemporaneous prescription compounding of oral and topical preparations. **Non-medicinal ingredient:** talc. Bottles of 1 billion units. Non-sterile. The resultant suspension contains no preservatives and should be used immediately. Protect from light. Store under refrigeration between 2 - 8°C.

Keep these products and all medicine out of the reach of children.