

## **PRESCRIBING INFORMATION**

### **PrTEVA-NYSTATIN**

**Nystatin oral suspension USP  
100 000 units / mL**

**Nystatin Vaginal cream USP  
100 000 units / g**

### **Prratio-NYSTATIN**

**Nystatin cream USP  
100 000 units / g**

**Nystatin ointment USP  
100 000 units / g  
Antifungal / Antibiotic**

**Teva Canada Limited  
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Toronto, Ontario  
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## **INDICATIONS AND CLINICAL USE**

### **Oral suspension:**

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

### **Vaginal cream:**

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.

## **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.

Rash and hypersensitivity reactions may occur.

### **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.

**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.

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

**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 and 1L with calibrated dropper. 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.

**Topical cream:** Each g contains: nystatin 100 000 units. **Non-medicinal ingredients in alphabetical order:** emulsifying wax, glycerin, isopropyl myristate, lactic acid, purified water, sodium hydroxide 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.

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