

1.6.3 Patient information leaflet (PIL):
Enclosed herewith

Dawastin®

Nystatin oral suspension

Composition

Each ml contains Nystatin BP.....100, 000 I U

Pharmacology

Nystatin is a polyene antifungal antibiotic which is both fungistatic and fungicidal in vitro against a wide spectrum of yeasts and yeast like fungi. It acts by binding to sterols in the cell membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components.

Nystatin is obtained from *streptomyces noursei* and is the first well tolerated antifungal antibiotic of dependable efficacy for the treatment of cutaneous, oral and intestinal infections caused by candida (*monilia*) albicans and other candida species. It exhibits no appreciable activity against bacteria.

Nystatin provides specific therapy for all localized forms of candidiasis. Symptomatic relief is rapid, often occurring within 24 to 72 hours after the initiation of treatment. Cure is affected both clinically and mycologically in most cases of localized candidiasis.

Pharmacokinetics

Gastrointestinal absorption of nystatin is insignificant. Most orally administered nystatin is passed unchanged in the stool.

Significant concentrations of nystatin may appear occasionally in the plasma of patients with renal insufficiency during oral therapy with conventional dosage forms. Mean nystatin concentrations in excess of those required in vitro to inhibit growth of clinically significant candida persisted in saliva for approximately 2 hours after the start of oral dissolution of 400,000 units of nystatin administered simultaneously to 12 healthy volunteers.

Indications

Nystatin is used in the prophylaxis and treatment of candidiasis of the mucous membranes, intestinal or oesophageal candidiasis. Nystatin has also been administered with antibiotics in various regimens to suppress the overgrowth of gastrointestinal flora. Nystatin is also used for the treatment of lesions of the mouth.

Contraindications

Nystatin is contraindicated in patients with a history of hypersensitivity to any of its components.

Side effects

Nausea, vomiting, and diarrhoea have occasionally been reported after oral use of nystatin.

Oral irritation or sensitisation may occur. Rashes, including urticaria, have occurred and Stevens-Johnson syndrome has been reported rarely. Irritation may occur rarely after the topical use of nystatin. Generalized pustular eruptions were reported in 3 patients after oral nystatin.

Subsequent sensitivity testing revealed delayed (type IV) hypersensitivity to nystatin.

Precautions

The potency of this product cannot last for longer than 90 days after the container is first opened.

Keep in airtight containers and use the suspension within one month (30 days) after opening the container.

Dosage

Infants:

2ml of Dawastin (200,000 units of Nystatin) four times daily (1ml in each side of the mouth).

Note: Limited clinical studies in premature and low birth weight infants indicate that 1ml four times daily is effective.

Children and adults:

4-6ml of Dawastin (400,000 to 600,000 units nystatin) four times daily (one half of dose in each side of the mouth).

The preparation should be retained in the mouth for as long as possible before swallowing.

Overdosage and Treatment

Oral doses of Nystatin in excess of five million units daily have caused nausea and gastrointestinal upsets.

There have been no reports of serious toxic effects or super infections.

In case of overdosage, symptomatic therapy (e.g. gastric lavage) and general supportive measures are recommended.

Storage

Store in a dry place below 30°C and protect from light.

Keep out of reach of children.

Presentation

Dawastin is available in amber coloured bottles containing 12ml and 30ml of suspension, the pack also contains a graduated dropping device.

Manufactured By:



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Ref: Lf/DL/ Dawastin/02

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1.6.4. Mock-ups and specimens: *Not applicable.*

1.6.5 Information by experts

Enclosed herewith