Alert

The Antimicrobial Stewardship Team listed this drug under the following category: Unrestricted. Nystatin is not suitable for the treatment of invasive fungal disease.

Indication

1) Prophylaxis in infants at high risk for invasive fungal infections.
   Criteria for prophylaxis should be determined by local policy. Indications may include:
   Infants ≤ 32 weeks gestation at birth or < 1500 g birth weight or larger infants with risk factors including use of broad spectrum antibiotics, having a central venous access device (PICC/UVC/CVC), receiving parenteral nutrition or inhaled steroids.

2) Treatment of mucocutaneous candidiasis.

Action

Fungicidal agent which works by combining with the sterol elements of fungal cell membranes causing cell death by producing increased cell wall permeability.

Drug Type

Polyene antibiotic.

Trade Name

Nilstat oral drops, Mycostatin oral drops. Mycostatin topical cream.

Presentation

1. Oral drops (100,000 units/mL)
2. Topical cream (for cutaneous application)

Dosage/Interval

1. Prophylaxis of invasive fungal infection:
   1 mL of oral drops every 8 hours.
2. Treatment of oral candidiasis (thrush):
   1 mL of oral drops every 6 hours. Can be given more frequently in severe/resistant thrush.
3. Treatment of candida dermatitis:
   Local application of cream twice a day. Can be applied more frequently in severe/resistant cases.

Route

1. Oral
2. Topical application on the skin

Maximum Daily Dose

Not required.

Preparation/Dilution

Not required.

Administration

1. Prophylaxis with oral drops: Shake well before withdrawing the dose. Administer after a feed (if not NBM). Use the whole dose to saturate cotton bud and paint the inside of the mouth. Alternatively, 0.5 mL can be given through the feeding tube and flushed with a bolus of air (1 mL for a 5 Fg tube, 2 mL for an 8 Fg tube). Use the other 0.5 mL to saturate a cotton bud and paint the inside of the infant’s mouth.
2. Treatment of oral thrush with the oral drops: Use the entire dose to paint the inside of the infant’s mouth.
3. Treatment of dermatitis: Dry the skin thoroughly and apply the cream to the affected area. Leave the skin exposed if feasible. May need to be reapplied if the cream is wiped off during skin care.

Monitoring

Not required.

Contraindications

Known hypersensitivity to nystatin or any other ingredients (sucrose, methyl hydroxybenzoate, propyl hydroxybenzoate)

Precautions

None

Drug Interactions

Not applicable

Adverse Reactions

Generally well tolerated. Large doses may produce gastrointestinal upset (vomiting, diarrhoea). Rarely, may lead to rashes e.g. urticaria. Type 4 hypersensitivity reactions have been reported in adults.

Compatibility

No information

Incompatibility

Do not mix in the syringe with any other medication.

Stability

Stable until expiry date on the bottle/tube.

Storage

At room temperature

Special Comments

Nil

Evidence summary

Efficacy

Prevention of invasive fungal infections
A systematic review of RCTs found oral nystatin to be highly effective in preventing invasive fungal
infection in VLBW infants with a relative risk of 0.16 when compared to placebo. A Cochrane meta-analysis found a statistically significant reduction in the incidence of invasive fungal infection (typical risk ratio 0.20, 95% CI 0.14-0.27) in very preterm VLBW infants when comparing oral/topical non-absorbed antifungal prophylaxis (nystatin or miconazole) with placebo or no drug. Substantial statistical heterogeneity was present though. (LOE 1A, GOR A)

A study from Australian and New Zealand NICUs reported that prophylactic oral nystatin is associated with a significantly lower incidence of fungal infection compared with no antifungal prophylaxis.

Treatment of mucocutaneous fungal infection

Boon et al reported a cure rate of 80% after 2 weeks with the dose of 400,000 units/day. In a randomised trial comparing nystatin suspension with miconazole gel in immunocompetent infants for treatment of oropharyngeal candidiasis, Hoppe reported miconazole gel to be significantly superior with regard to efficacy, rapidity of achieving cure and oropharyngeal yeast eradication. Relapses and side effects were no different between miconazole and nystatin. However, miconazole gel is contraindicated in those under 6 months of age due to risk of airway obstruction from gel.

Safety

Acute generalised exanthematous pustulosis has been described following oral nystatin therapy.

References