



MONOGRAPH

Nystatin Monograph - Paediatric

Scope (Staff):	Medical, Pharmacy, Nursing
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this [DISCLAIMER](#)

QUICKLINKS

Dosage/Dosage Adjustments	Administration	Compatibility	Monitoring
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DRUG CLASS

Polyene antifungal.⁽¹⁾

INDICATIONS AND RESTRICTIONS

Nystatin 100,000units/gram 15gram tube: **Special access scheme product**. [SAS application\(s\)](#) must be completed in accordance to the [TGA regulations](#).

Oral: Unrestricted (green) antifungal

This is not a restricted agent. Follow standard ChAMP guidelines where appropriate.

CONTRAINDICATIONS

- Hypersensitivity to nystatin or any component of the formulation.^(2, 3)

PRECAUTIONS

- Oral nystatin should NOT be used in the treatment of systemic fungal infections as it is not absorbed from the gastrointestinal tract.⁽²⁾
- Topical nystatin is generally not used in the treatment of oropharyngeal candidiasis in immunosuppressed patients. An alternative agent should be considered.⁽⁴⁾

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- 100,000 units/mL oral liquid (24mL)
- 100,000 units/gram topical cream (SAS) (15g)

Imprest location: [Formulary One](#)

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: [Refer to Neonatal Medication Protocols](#)

Prophylaxis in high risk neonates: Refer to

- [ChAMP Antifungal Prophylaxis Guideline](#)
- [KEMH neonatal protocols](#)

Oral liquid:

- **Prophylaxis of Oropharyngeal candidiasis:**

≥4 weeks to 18 years of age: 100,000 units (1mL) four times a day.⁽⁵⁾

- **Treatment of Oropharyngeal candidiasis:**

≥4 weeks to 18 years of age: 100,000 units (1mL) four times a day. Dose can be increased up to 500,000 units four times a day if severe.⁽⁴⁾

Topical Cream:

- **Treatment of Cutaneous candidiasis:**

≥4 weeks to 18 years: Apply cream topically to the affected area(s) two to four times daily.^(3, 6)

Renal impairment:

- No dosage adjustments required in renal impairment.⁽⁵⁾

Hepatic impairment:

- No dosage adjustments required in hepatic impairment.⁽⁵⁾

ADMINISTRATION

Oral suspension (for prophylaxis or treatment of oropharyngeal candidiasis):

- The oral suspension should be shaken well before measuring the required dose.⁽⁵⁾
- The suspension should be swished around the mouth for as long as comfortable before being swallowed. For younger patients in whom this is not possible, the suspension can be dropped or painted onto the affected areas.^(1, 5, 7)
- Administer half the dose on each side of the mouth and avoid feeding infants for 5 to 10

minutes after the dose.⁽⁵⁾

- Treatment should be continued for 2 to 3 days after symptoms have resolved, the usual treatment duration is 7 to 14 days.^(2, 5, 8)
- For neonates with nasogastric or nasojejunal tubes half the dose should be given orally and half via the enteral feeding tube.^(5, 7)

MONITORING

- Monitor for resolution of symptoms and if appropriate take fungal cultures.^(3, 5)

ADVERSE EFFECTS

Common: nausea, vomiting, diarrhoea, (more common with higher doses) dyspepsia, oral irritation, stomach pain. ^(1, 2, 5, 9)

Rare: Rash, urticaria, Stevens-Johnson syndrome, hypersensitivity, facial oedema, bronchospasm and angioedema.^(2, 5, 9) Topical use may result in skin irritation, burning, itching, rash.⁽⁵⁾

STORAGE

Nystatin should be stored below 25°C.⁽²⁾

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. [Clinical Pharmacology](#)), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **nystatin**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

[Antimicrobial Stewardship Policy](#)

[ChAMP Empiric Guidelines and Monographs](#)



[KEMH Neonatal Medication Protocols](#)

References

1. Rossi S, editor. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2021.
2. MIMS Australia. MIMS online [full product information]. St Leonards, N.S.W: CMP Medica Australia.; 2021. p. 1v. (various pagings).
3. IBM Micromedex [Internet]. Truven Health Analytics. 2021 [cited 08/02/2022]. Available from: <http://www-micromedexsolutions-com.pklibresources.health.wa.gov.au/micromedex2/librarian>.
4. Royal Australian College of General Practitioners, Pharmaceutical Society of Australia,

- Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists. AMH: Children's Dosing Companion. Adelaide: Australian Medicines Handbook Pty Ltd; 2020.
5. Clinical Pharmacology [Internet]. Elsevier BV. 2021 [cited 08/02/2022]. Available from: <http://www.clinicalpharmacology-ip.com.pklibresources.health.wa.gov.au/default.aspx>.
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 7. Expert Opinion. Infectious Diseases.
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 9. Paediatric Formulary Committee. BNF for Children: 2021. London: BMJ Group Pharmaceutical Press; 2021.

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