MONOGRAPH

Fluconazole 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

DRUG CLASS

Azole antifungal.[1-3]

INDICATIONS AND RESTRICTIONS

Fluconazole is indicated in the treatment of mucocutaneous and systemic fungal infections due to yeasts (some *Candida* spp. and Cryptococcus).[3, 4]

Fluconazole is also used in the primary and secondary prevention of candida infection in immunocompromised patients.[3]

Oral and IV: Monitored (orange) antifungal

Fluconazole is indicated for use as per the indications stipulated in Formulary One. For any other use, phone approval must be obtained from ChAMP before prescribing as per the Children's Antimicrobial Management Program (ChAMP) Policy.

CONTRAINDICATIONS

- Hypersensitivity to fluconazole, related azole antifungal or any component of the formulation.[3, 5-7]
- Fluconazole has been shown to prolong the QT interval and should not be used in combination with other drugs that prolong the QT interval. It should be used with caution in

patients with potentially pro-arrhythmic conditions. [3, 5-9]

- Fluconazole is an inhibitor of CYP3A4, CYP2C19 and CYP2C9 review and assessment of possible drug interactions is recommended prior to prescribing.[6, 9]

PRECAUTIONS

- Care should be taken in patients with hepatic impairment due to the risk of serious liver toxicity.[5, 6]
- Each 200 mg (100 mL) of IV solution contains 15 mmol of sodium.[5]
- Use in pregnancy should be avoided and effective contraceptive should be used throughout therapy and for at least one week after the final dose.[6, 7]
- Fluconazole capsules should not be used in patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption due to the lactose content of the capsules.[5]
- Fluconazole powder for oral suspension should not be used in patients with hereditary fructose, glucose/ galactose malabsorption and sucrase-isomaltase deficiency.[5]

FORMULATIONS

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

- 2 mg/mL solution for injection vial
- 50 mg, 100 mg and 200 mg capsules
- 10 mg/mL oral suspension

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Neonates: Refer to Neonatal Medication Protocols

Children ≥ 4 weeks:

Candidaemia or other systemic infections:

Intravenous:

- 12 mg/kg/dose (to a maximum of 800 mg) once daily[6]
- Switch to oral therapy should only be done in consultation with infectious diseases.

***Superficial and oral candidiasis*:**

Oral or Intravenous:

- 6 mg/kg/dose (to a maximum of 200 mg) once daily.[1, 9]
- For oesophageal infection, the higher dose of 12 mg/kg/dose (to a maximum of 600 mg) once daily may be used.[9]

Vaginal candidiasis:

- **Oral:** 150 mg as a single dose (in post-pubertal females).[1, 8]

Prophylaxis (immunocompromised patients):

- **Oral or Intravenous :** 3 to 12 mg/kg/dose (to a maximum of 400 mg) once daily.[1]
- Fluconazole has excellent oral bioavailability – consider switching to oral dosing as soon as clinically appropriate. Fluconazole has good tissue and CNS penetration.[4, 9]

Dosing in Overweight and Obese Children: Dose based on total body weight.[10]

Renal impairment:

eGFR calculator

- CrCl: > 50 mL/minute/1.73 m^2: Normal dose
- CrCl: 10-50 mL/minute/1.73 m^2: Give the recommended dose on day one then give 50% of this dose 24 hourly. [6, 9]
- CrCl: <10 mL/minute/1.73 m^2 : Give the recommended dose on day one then give 50% of this dose 48 hourly.[6]
- No dose reduction is required for single dose therapy.[6, 9]

Hepatic impairment:

- No dosage adjustment is required in hepatic impairment. Ongoing monitoring of hepatic function is required due to the risk of severe hepatic toxicity.[6, 9]

RECONSTITUTION & ADMINISTRATION

Oral reconstitution:

- Tap the closed bottle several times to loosen the powder, add the volume of purified water according to the manufacturer's instruction and shake well.[5]
- Store reconstituted suspension between 5 and 30 ºC and discard any remaining suspension after 14 days.[5]

Administration:

Intravenous infusion:

- Infuse undiluted (2 mg/mL) over at least 1 to 2 hours.[2]
- Doses ≥8 mg/kg should be administered over 2 hours. [2, 9]
- Do not exceed a rate of 200 mg/hour. [2, 6, 9]
- Fluconazole has good oral bioavailability, switch to oral therapy when clinically suitable. Confirm oral switch with Infectious Diseases for patients with invasive Candidaemia.[5, 9]

Oral:

- May be administered with or without food.[5, 6, 9]
- Shake the suspension well before measuring out the dose.[5, 6, 9]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids:

- Glucose 5%
- Sodium chloride 0.9%
- Hartmann's
- Ringer's Solution.[2]

Compatible at Y-site:

Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

MONITORING

- Renal, hepatic, haematological function, platelets and potassium levels should be monitored at baseline and routinely with prolonged therapy (i.e. longer than 7 days).[3, 6, 8, 9]
- Patients should be counselled to report any unusual tiredness, nausea or loss of appetite, dark urine or pale faeces or any signs of jaundice whilst taking fluconazole.[3]
- ECG monitoring should also be conducted in those patients with pro-arrhythmic conditions or additional medications that may prolong the QT interval.[6]

Therapeutic Drug Monitoring:

- Therapeutic drug monitoring of fluconazole may be indicated in certain clinical circumstances (e.g. critically ill patients, those with altered renal function or to confirm compliance with medication). Discuss with Infectious Diseases team.[4, 11]

Collection tube:

- EDTA (lavender)[12]
- Minimum volume required 200 microlitres[12]
- Sample should be taken as a trough level in the 60 minutes before administration of the next dose.[12]

ADVERSE EFFECTS

Common: rash, headache, dizziness, nausea, vomiting, abdominal pain, diarrhoea, elevated liver enzymes.[3, 8]

Infrequent: anorexia, fatigue, flatulence, altered taste, seizure, constipation.[3, 8]

Rare: oliguria, alopecia, hypokalaemia, , seizures, severe cutaneous adverse reactions (SCARs), prolonged QT interval, torsades de pointes, thrombocytopenia, blood dyscrasias, serious hepatotoxicity including hepatic failure, anaphylactic/anaphylactoid reactions, peripheral neuropathy, dyslipidaemia.[3, 8]

STORAGE

- **Vials**: Store below 30˚C, do not refrigerate and protect from light.[2, 5]
- **Capsules:** Store below 30˚C.[5]
- **Powder for oral suspension**: Prior to reconstitution, store below 30˚C. After reconstitution, store between 5 ˚C and 30 ˚C for up to 14 days.[5, 6, 9]

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 **fluconazole**. 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. 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; 2022.
2. Symons K. Wong Ee. Australian injectable drugs handbook. Abbotsford: The Society of Hospital Pharmacists of Australia; 2023.
3. Australian Medicines Handbook. Adelaide, S. Aust.: Australian Medicines Handbook; 2025 [cited 2025 6th March]. Available from: https://amhonline-amh-net-au.pklibresources.health.wa.gov.au/.
4. Antibiotic Writing Group. Therapeutic Guidelines - Antibiotic. West Melbourne: Therapeutic Guidelines Ltd; 2022. Available from: https://tgldcdp-tg-org-au.pklibresources.health.wa.gov.au/etgAccess.
5. AusDI [Internet]. Health Communication Network Pty Ltd. 2025 [cited 2025 March 6th].
6. Clinical Pharmacology powered by ClinicalKey [Internet]. Elsvier. 2025 [cited 2025 March 6th]. Available from: https://www-clinicalkey-com.pklibresources.health.wa.gov.au/pharmacology/.
7. IBM Micromedex [Internet]. Truven Health Analytics. 2025 [cited 2025 February 18th]. Available from: http://www-micromedexsolutions-com.pklibresources.health.wa.gov.au/micromedex2/librarian.
8. Paediatric Formulary Committee. BNF for Children: 2025. London: BMJ Group Pharmaceutical Press; 2025.
9. Up To Date - Paediatric Drug information [Internet]. Lexicomp. 2025 [cited 2025 March 6th]. Available from: https://www-uptodate-com.pklibresources.health.wa.gov.au/contents/table-of-contents/drug-information/pediatric-drug-information.

10. Castro-Balado A, Varela-Rey I, Mejuto B, Mondelo-García C, Zarra-Ferro I, Rodríguez-Jato T, et al. Updated antimicrobial dosing recommendations for obese patients. Antimicrobial Agents and Chemotherapy. 2024;68(5):e01719-23.
11. Chau MM, Daveson K, Alffenaar J-WC, Gwee A, Ho SA, Marriott DJE, et al. Consensus guidelines for optimising antifungal drug delivery and monitoring to avoid toxicity and improve outcomes in patients with haematological malignancy and haemopoietic stem cell transplant recipients, 2021. Internal Medicine Journal. 2021;51(S7):37-66.
12. PathWest. PathWest - test directory Perth2025 [cited 2025. Available from: https://pathwesttd.health.wa.gov.au/testdirectory/.

This document can be made available in alternative formats on request.

File Path:	*W:\Safety & Quality\CAHS\CLOVERS MEDICAL Pharmacy\Procedures Protocols and Guidelines\ChAMP\Word*		
Document Owner:	Head of Department – Infectious Diseases		
Reviewer / Team:	Children's Antimicrobial Management Program Pharmacist		
Date First Issued:	October 2013	Last Reviewed:	February 2025
Amendment Dates:	February 2020, December 2021, February 2025	Next Review Date:	March 2028
Approved by:	CAHS Drug and Therapeutics Committee	Date:	April 2025
Endorsed by:	Chair, CAHS Drug and Therapeutics Committee	Date:	April 2025
Aboriginal Impact Statement and Declaration (ISD)		Date ISD approved:	August 2023
Standards Applicable:	NSQHS Standards: NSMHS: N/A Child Safe Standards: N/A		

Printed or personally saved electronic copies of this document are considered uncontrolled

Healthy kids, healthy communities

Compassion | Excellence | Collaboration | Accountability | Equity | Respect

Neonatology | Community Health | Mental Health | Perth Children's Hospital