



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
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DRUG CLASS

Azole antifungal⁽¹⁾

INDICATIONS AND RESTRICTIONS

Fluconazole is indicated in the treatment of systemic fungal infections due to yeasts (some *Candida* spp. and *Cryptococcus*) and as an alternative treatment for dermatophyte infections not involving the scalp or nails.⁽¹⁾

Fluconazole is also used in the primary and secondary prevention of candida infection in immunocompromised patients.⁽¹⁾

Oral and IV: Monitored (orange) antifungal

- If the use is consistent with a standard approved indication, this must be communicated to ChAMP by documenting that indication on all prescriptions (inpatient and outpatient).
- The ChAMP team will review if ongoing therapy is required and/or if the order does not meet [ChAMP Standard Indications](#)
- If use is not for a standard approved indication, phone approval must be obtained from ChAMP before prescribing.

CONTRAINDICATIONS

- Hypersensitivity to fluconazole, related azole antifungal or any component of the formulation.⁽²⁻⁵⁾
- Fluconazole has been shown to prolong the QT interval and should not be used in combination with other drugs that prolong the QT interval and drugs that are metabolised by CYP3A4.^(1-3, 5)

PRECAUTIONS

- Care should be taken in patients with hepatic impairment due to the risk of serious liver toxicity.^(3, 6)
- Each 200mg (100mL) of IV solution contains 15mmol of sodium.⁽⁷⁾
- Use in pregnancy should be avoided and effective contraceptive should be used throughout therapy and for at least one week after the final dose. Single dose therapy should be avoided in the first trimester due to a potential risk of spontaneous abortion.^(1, 4-6)

FORMULATIONS

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

- 100mg/50mL solution for injection vial
- 50mg, 100mg and 200mg capsules
- 50mg/5mL oral suspension

Imprest location: [Formulary One](#)

DOSAGE & DOSAGE ADJUSTMENTS

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

Children ≥4 weeks:

Candidaemia or other systemic infections:

IV: 12mg/kg/dose (to a maximum of 800mg) once daily^(1, 3) Step-down to oral therapy should only be done in consultation with infectious diseases.

Superficial and oral candidiasis:

- **Oral/IV:** 6mg/kg/dose (to a maximum of 200mg) once daily for one day, then 3mg/kg/dose (to a maximum of 100mg) once daily thereafter.⁽⁸⁾
- For oesophageal infection, the higher dose of 12mg/kg/dose (to a maximum of 400mg) once daily may be used.⁽⁸⁾

Vaginal candidiasis:

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

Prophylaxis (immunocompromised patients):

- **Oral/IV:** 3 to 12mg/kg/dose (to a maximum of 400mg) once daily.⁽⁸⁾
- Fluconazole has excellent oral bioavailability – consider switching to oral dosing as soon as clinically appropriate.⁽⁹⁾ Fluconazole has good tissue and CNS penetration.⁽¹⁰⁾

Renal impairment:

- [eGFR calculator](#)
- CrCl: > 50mL/minute : Normal dose
- CrCl: 10-50mL/minute: Give the normal loading dose then use 50% of the recommended maintenance dose 24 hourly.⁽³⁾
- CrCl: <10mL/minute : Give the normal loading dose then use 50% of the recommended maintenance dose 48 hourly.⁽³⁾
- No dose reduction is required for single dose therapy.^(3, 5)

Hepatic impairment:

No dosage adjustment is required in hepatic impairment. However ongoing monitoring of hepatic function is required due to the risk of severe hepatic toxicity.^(3, 5, 6)

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 to the powder and shake well.
- Store reconstituted solution between 5 and 30°C and discard any remaining suspension after 14 days.⁽⁶⁾

Administration:**IV infusion:**

- Infuse undiluted (2mg/mL) over at least 60 minutes.^(5, 7)
- Doses \geq 8mg/kg should be administered over 2 hours.^(4, 5, 7, 9)
- Do not exceed a rate of 200mg/hour.^(4, 7)

Oral:

- May be administered with or without food.^(4, 5)
- Shake the suspension well before measuring out the dose.^(5, 6)

COMPATIBILITY (LIST IS NOT EXHAUSTIVE)**Compatible fluids:**

- Glucose 5%
- Sodium chloride 0.9%
- Hartmann's
- Ringer's Solution.⁽⁷⁾

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).^(1, 6, 11)
- 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.⁽¹⁾
- ECG monitoring should also be conducted in those patients with pro-arrhythmic conditions or additional medications that may prolong the QT interval.

ADVERSE EFFECTS

Common: rash, headache, nausea, vomiting, abdominal pain, diarrhoea, elevated liver enzymes.^(1, 11)

Infrequent: anorexia, fatigue, dizziness, flatulence, altered taste.^(1, 11)

Rare: oliguria, alopecia, hypokalaemia, dizziness, constipation, seizures, severe cutaneous adverse reactions (SCARs), prolonged QT interval, torsades de pointes, thrombocytopenia, blood dyscrasias, serious hepatotoxicity including hepatic failure, anaphylactic/anaphylactoid reactions.^(1, 3, 6, 11)

STORAGE

- **Vials:** Store below 25°C, do not refrigerate and protect from light.^(5, 7)
- **Capsules:** Store below 30°C.⁽⁶⁾
- **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⁾

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

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