


FLUCONAZOLE

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Formulary: Restricted Requires Neonatologist or Microbiologist review within 24 hours of initiation.	
Presentation	Vial: 200 mg/100 mL = 2 mg/mL Oral suspension: 50 mg/5 mL = 10 mg/mL
Classification	Azole antifungal
Indication	<ul style="list-style-type: none"> Treatment of systemic candida infections. Prophylaxis against candida colonisation in very low birthweight infants. Treatment of oral candidiasis if inadequate response to topical antifungals.
Special Considerations	<ul style="list-style-type: none"> Known hypersensitivity to fluconazole or related azole antifungal or any excipient of the product. Fluconazole should not be used in combination with other QT-prolonging drugs metabolized by CYP3A4 (e.g. erythromycin) – <i>contact pharmacy for further information.</i> Caution in patients with hepatic impairment due to the risk of serious liver toxicity. Each 100 mL of IV fluconazole solution contains 15 mmol of sodium.
Monitoring	<ul style="list-style-type: none"> Liver function (AST, ALT, alkaline phosphates) and renal function tests. Electrolytes, particularly serum potassium. Full blood count. ECG monitoring should also be conducted in those patients with pro-arrhythmic conditions or additional medications that may prolong the QT interval.
Compatibility	Fluids: Sodium chloride 0.9%, glucose 5%. Y-site: Aciclovir, amikacin, amiodarone, cefazolin, dexamethasone, erythromycin, fentanyl, ganciclovir, gentamicin, heparin sodium, hydrocortisone, lidocaine, linezolid, magnesium sulfate, meropenem, metronidazole, midazolam, morphine sulfate, piperacillin-tazobactam, sodium bicarbonate, tobramycin, vancomycin, zidovudine. <i>This list is not exhaustive, contact pharmacy.</i>
Incompatibility	Y-site: Calcium gluconate, ceftriaxone, digoxin, furosemide. <i>This list is not exhaustive, contact pharmacy.</i>
Interactions	<ul style="list-style-type: none"> Fluconazole has been shown to prolong the QT interval; it should be used with caution in combination with other drugs that may also prolong the QT interval due to the increased risk of arrhythmias. Alters metabolism of phenytoin, barbiturates, caffeine, midazolam. Monitor levels of these drugs if used concomitantly for long periods.

Side Effects	Common: Rash, headache, nausea, vomiting, abdominal pain, diarrhoea, reversible elevated liver enzymes.
	Infrequent: Constipation, dizziness, altered taste, seizures.
	Rare: Hypokalaemia, thrombocytopenia, neutropenia, agranulocytosis, alopecia, severe cutaneous adverse reactions, serious hepatotoxicity including hepatic failure, anaphylactic/anaphylactoid reactions; prolonged QT interval, torsades de pointes (both very rare).
Storage & Stability	Vial: Store at room temperature, below 30°C. Protect from light. Powder for reconstitution: Store at room temperature, below 30 °C. <ul style="list-style-type: none"> Reconstituted suspension: Store between 5 and 30°C, do not freeze. Discard 14 days after reconstitution.
Comments	Prophylactic nystatin may be continued during treatment or prophylaxis with fluconazole, the decision to continue or cease nystatin should be made by the treating neonatologist. Nystatin can help with gut decolonisation of candida and can cover fluconazole resistant candida species.

ORAL	Presentation (for oral use)	Oral suspension: 50 mg/5 mL = 10 mg/mL	
	Dosage	<u>Treatment – systemic infection</u> <i>Consider a loading dose where appropriate. Without a loading dose, fluconazole takes 5 to 7 days to reach steady state concentrations.</i> Loading dose: 25 mg/kg/dose. Maintenance dose: 12 mg/kg/dose once daily. <i>Duration of treatment is dependent on clinical situation – consult microbiology.</i>	
		<u>Prophylaxis against candida colonisation</u> 6 mg/kg/dose twice weekly (every 3 to 4 days).	
		<u>Treatment - oral candidiasis</u> 3 mg/kg/dose once daily for 7 days.	
		Dose adjustment <ul style="list-style-type: none"> Renal impairment: Dose reduction or extended dosing intervals should be considered for neonates with renal impairment, consult microbiology. Hepatic impairment: Limited information, manufacturer advises caution. 	
	Preparation	Oral suspension: 50 mg/5 mL = 10 mg/mL Reconstitution: <ul style="list-style-type: none"> Tap bottle to loosen the powder. Add 24 mL of sterile water to the fluconazole powder for suspension. Shake well. <i>Concentration now equal to 50 mg/5 mL = 10 mg/mL.</i>	
	Administration	<ul style="list-style-type: none"> Shake well before use. Draw prescribed dose into oral/enteral syringe. Can be given Oral/OGT/NGT. May be given anytime in relation to feeds. 	



INTRAVENOUS INFUSION

Presentation (for IV use)	Vial: 200 mg/100 mL = 2 mg/mL Available from CIVAS (KEMH & PCH)
Dosage	<u>Treatment – systemic infection</u> <i>Consider a loading dose where appropriate. Without a loading dose, fluconazole takes 5 to 7 days to reach steady state concentrations.</i> Loading dose: 25 mg/kg/dose. Maintenance dose: 12 mg/kg/dose once daily. <i>Duration of treatment is dependent on clinical situation – consult microbiology.</i>
	<u>Prophylaxis against candida colonisation</u> 6 mg/kg/dose twice weekly (every 3 to 4 days).
	<u>Treatment - oral candidiasis</u> 3 mg/kg/dose once daily for 7 days.
	Dose adjustment <ul style="list-style-type: none">• Renal impairment: Dose reduction or extended dosing intervals should be considered for neonates with renal impairment, consult microbiology.• Hepatic impairment: Limited information, manufacturer advises caution.
	Preparation Use undiluted.
Administration	IV infusion: <ul style="list-style-type: none">• Infuse via syringe driver pump over 1 to 2 hours.• Infuse doses greater than 6 mg/kg over 2 hours.

Related Policies, Procedures, and Guidelines

Clinical Practice Guidelines:

[CAHS Neonatology – Candida Infections](#)

[PCH ChAMP – Antifungal Prophylaxis](#)

Pharmaceutical and Medicines Management Guidelines:

[CAHS Neonatology – Medication Administration Guideline](#)

[WNHS Cold Chain Management for Medications and Vaccines](#)

[CAHS Medication Refrigerators and Freezers](#)

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