



NEONATAL

FLUCONAZOLE

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

Restricted: Requires Neonatologist or Microbiologist review within 24 hours of initiation

Presentation	Vial: 200mg/100mL = 2mg/mL Oral suspension: 50mg/5mL= 10mg/mL							
Classification	Azole antifungal							
Indication	Treatment of systemic candida infections Prophylaxis against candida colonisation in very low birthweight infants Treatment of oral candidiasis if inadequate response to topical antifungals							
Contraindications	Known hypersensitivity to fluconazole or related azole antifungal or any excipient of the product Fluconazole should not be used in combination with other drugs that prolong the QT interval AND are metabolised by CYP3A4 – <i>contact pharmacy for further information</i> Caution in patients with hepatic impairment due to the risk of serious liver toxicity.							
Dose	<p><u>Treatment - Systemic infections</u></p> <p>Oral/IV:</p> <table border="1"> <tr> <td>Consider a loading dose <i>(where appropriate)</i></td> <td>25mg/kg/dose</td> </tr> <tr> <td>Maintenance dose</td> <td>12mg/kg/dose daily <i>Duration is dependent on clinical situation - Consult microbiology</i></td> </tr> </table> <p><u>Prophylaxis</u></p> <p>Oral/IV:</p> <table border="1"> <tr> <td>Dose</td> <td>6mg/kg/dose TWICE Weekly</td> </tr> </table>		Consider a loading dose <i>(where appropriate)</i>	25mg/kg/dose	Maintenance dose	12mg/kg/dose daily <i>Duration is dependent on clinical situation - Consult microbiology</i>	Dose	6mg/kg/dose TWICE Weekly
Consider a loading dose <i>(where appropriate)</i>	25mg/kg/dose							
Maintenance dose	12mg/kg/dose daily <i>Duration is dependent on clinical situation - Consult microbiology</i>							
Dose	6mg/kg/dose TWICE Weekly							

	<p>Oral Candidiasis <i>(If inadequate response to topical antifungals)</i></p> <p>Oral:</p> <table border="1"> <tr> <td>Dose</td> <td>3mg/kg/dose daily for 7 days</td> </tr> </table>	Dose	3mg/kg/dose daily for 7 days
Dose	3mg/kg/dose daily for 7 days		
Dose Adjustment	Dose reduction is recommended in patients with renal impairment. <i>Consult Microbiology</i>		
Monitoring	Liver function (AST, ALT, alkaline phosphates), renal function tests, serum potassium, CBC, platelets for long term use		
Guidelines & Resources	WNHS Policy: Antimicrobial Stewardship		
Compatible Fluids	Use undiluted Glucose 5%, Sodium chloride 0.9%		
Preparation	<p>IV: Available from CIVAS (KEMH & PCH) Use undiluted</p> <p>Oral: Reconstitution: Add 24mL of Water for Irrigation to the powder for suspension in the bottle. Shake well. Concentration is 50mg/5mL = <u>10mg/mL</u> Discard any remaining suspension after 14 days</p>		
Administration	<p>IV Infusion: Infuse over 1 to 2 hours Infuse doses greater than 6mg/kg over 2 hours Maximum rate: 200mg/hour</p> <p>Oral: May be given at any time with regard to feeds</p>		
Adverse Reactions	<p>Common: rash, headache, dizziness, nausea, vomiting, abdominal pain, diarrhoea, reversible elevated liver enzymes</p> <p>Rare: oliguria, hypokalaemia, dizziness, seizures, Stevens-Johnson syndrome; prolonged QT interval, torsades de pointes (both very rare)</p>		
Storage	<p>Vial: Store at room temperature - below 25°C, protect from light</p> <p>Powder for reconstitution: Store at room temperature - below 25°C</p>		

	<p>Reconstituted suspension: Refrigerate - do not freeze</p> <p>Discard 14 days after reconstitution</p>
Interactions	<p>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</p> <p>Alters metabolism of phenytoin, barbiturates, caffeine, midazolam. Monitor levels of these drugs if used concomitantly for long periods.</p>
Notes	100mL of fluconazole contains 15mmol of sodium
References	<p>Society of Hospital Pharmacists of Australia. Fluconazole. In: Australian Injectable Drugs Handbook [Internet]. [St Leonards, New South Wales]: Health Communication Network; 2019 [cited 2019 August 12]. Available from: http://aidh.hcn.com.au</p> <p>Lilley L, Legge D. Paediatric injectable guidelines. 5th ed. Melbourne (Victoria): The Royal Children's Hospital; 2019. 90</p> <p>Truven Health Analytics. Fluconazole. In: NeoFax [Internet]. Greenwood Village (CO): Truven Health Analytics; 2019 [cited 2019 August 12]. Available from: https://neofax.micromedexsolutions.com/Clinical pharmacology</p> <p>Takemoto CK, Hodding JH, Kraus DM. Pediatric & neonatal dosage handbook with international trade names index : a universal resource for clinicians treating pediatric and neonatal patients. 24th ed. Hudson (Ohio): Lexicomp; 2401. 2, p851.</p> <p>Australian Medicines Handbook. Fluconazole. In: Australian Medicines Handbook [Internet]. Adelaide (South Australia): Australian Medicines Handbook; 2019 [cited 2019 August 14]. Available from: https://amhonline.amh.net.au/</p> <p>MIMS Australia. Fluconazole. In: MIMS Online [Internet]. St Leonards (New South Wales): MIMS Australia; 2019 [cited 2019 August 14]. Available from: https://www.mimsonline.com.au</p> <p>Pammi et al. Section editors: Edward M, Puopolo K; Deputy editor: Armsby C. Treatment of Candida Infections in Neonates. UpToDate June 2023</p> <p>Goins RA et al. Comparison of fluconazole and nystatin oral suspensions for treatment of oral candidiasis in infants. Ped Inf Dis J 2002; 21:1165</p>

Document owner:	Head of Department - Neonatology		
Author / Reviewer:	KEMH & PCH Pharmacy / Neonatology Directorate		
Version Info	Version 3.0: Full review (October 2019) Version 3.1: Oral candidiasis dose added (18/09/2023)		
Date first issued:	December 2008	Version:	3.1
Last reviewed:	October 2019	Next review date:	October 2024
Endorsed by:	Neonatal Directorate Management Group	Date:	26/09/2023

Standards Applicable:	NSQHS Standards: 1  Governance 3  Infection Control 4  Medication Safety;
Printed or personally saved electronic copies of this document are considered uncontrolled. Access the current version from the WNHS website.	

© Department of Health Western Australia 2023