South Australian Neonatal Medication Guidelines

Fluconazole

2mg/mL injection, 10mg/mL oral mixture © Department of Health and Wellbeing, Government of South Australia. All rights reserved

This quideline provides advice of a general nature. This statewide quideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient's medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes:

- The use of interpreter services where necessary,
- Advising consumers of their choice and ensuring informed consent is obtained.
- Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
- Documenting all care in accordance with mandatory and local requirements

Dose and Indications

Treatment for suspected or proven systemic fungal infections

Intravenous Infusion, Oral

Loading dose

25 mg/kg loading dose, then commence maintenance dose 24 hours later

Maintenance dose

12 mg/kg every 24 hours



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Prophylaxis for systemic fungal infections

Intravenous Infusion

3mg/kg on day one, then 72 hourly

Anti-fungal prophylaxis with IV fluconazole should be considered for eligible patients meeting one of the following criteria AND either nil by mouth or on minimal feeds:

- > Preterm neonates less than 1000g at birth with a central line
- > Preterm Neonates less than 1500g at birth and on prolonged antibiotic therapy
- Neonates with necrotising enterocolitis
- Neonates with surgical gastro intestinal conditions such as gastroschisis, intestinal atresia with anticipated need for prolonged parenteral nutrition

Discontinue fluconazole prophylaxis when nystatin therapy can be commenced. When the neonate is on partial oral feeds, nystatin can be used as the fungal prophylactic agent

Preparation and Administration

Intravenous Infusion

The intravenous solution contains 2mg/mL

Dose	3mg	6mg	12mg	18mg	24mg	30mg	36mg	42mg
Volume	1.5mL	3mL	6mL	9mL	12mL	15mL	18mL	21mL

Infuse undiluted over at least 1 hour

Doses greater than 6mg/kg are better infused over 2 hours

Discard any remaining solution.

Do not use if the solution is cloudy or precipitated

The intravenous solution contains 0.15mmol/mL of sodium

Oral

Refer to product information for reconstitution volume. The resulting solution after reconstitution contains 10mg/mL fluconazole.

Dose	3mg	6mg	12mg	18mg	24mg	30mg	36mg	42mg
Volume	0.3mL	0.6mL	1.2mL	1.8mL	2.4mL	3.0mL	3.6mL	4.2mL

Give with feeds to minimise gastrointestinal irritation.

The reconstituted solution is stable for 14 days at temperatures less than 30°C

Compatible Fluids

Glucose 5%, glucose 10%, sodium chloride 0.9%



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Adverse Effects

Common

Rash, vomiting, abdominal pain, diarrhoea, elevated liver enzymes

Infrequent

Constipation

Rare

Thrombocytopenia, other blood dyscrasias, serious hepatotoxicity, anaphylactic reactions, alopecia (especially with prolonged courses), oliguria, hypokalaemia, seizures, Stevens-Johnson syndrome; prolonged QT interval, torsades de pointes (both very rare)

Monitoring

- > Liver and renal function at baseline and at regular intervals, depending on dose and duration of treatment
- > Periodic electrolytes and full blood count

Practice Points

- > When using for treatment, use intravenous therapy only if oral administration is not possible, as oral absorption is excellent
- > Do not use to treat *C. krusei or C. glabrata*, as inherently resistant to fluconazole. Consult Infectious Diseases for advice
- > Fluconazole has good tissue penetration, including penetration into the CNS
- > Fluconazole is an enzyme inhibitor and may interact with other drugs. Consult clinical pharmacy for advice
- > Consider extending dosing interval to 48 hours (for treatment doses) if the neonate has poor renal function.
- > Use with caution in hepatic impairment due to the risk of serious liver toxicity

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References

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Document Ownership & History

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If so, which policy (title)?

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28/3/2022	V4.0	Domain Custodian, Clinical Governance, Safety and Quality	Formal Review
7/3/2017	V3.0	SA Health Safety and Quality Strategic Governance Committee	Review and update
10/2013	V2.0	SA Health Safety and Quality Strategic Governance Committee	Review, dosing changes
5/2013	V1.0	SA Maternal & Neonatal Clinical Network	Original SA Maternal & Neonatal Clinical Network approved version.