

Clinical Guideline

Fluconazole 2mg/mL injection, 10mg/mL oral mixture

Policy developed by: SA Maternal, Neonatal & Gynaecology Community of Practice

Approved SA Health Safety & Quality Strategic Governance Committee on: 07 March 2017

Next review due: 31 March 2020

Summary Fluconazole 2mg/mL injection, 10mg/mL oral mixture Clinical Practice Guideline for the administration of fluconazole to a neonate

Keywords Fluconazole, fungal infections, rash, vomiting, abdominal pain, diarrhoea, elevated liver enzymes, constipation, thrombocytopenia, dyscrasias, hepatotoxicity, oliguria, Hypokalemia, seizures, QT interval, torsades de pointes, clinical guideline, Fluconazole 2mg/mL injection, 10mg/mL oral mixture

Policy history Is this a new policy? **N**
Does this policy amend or update an existing policy? **Y 2.0**
Does this policy replace an existing policy? **Y**
If so, which policies? **fluconazole**

Applies to All Health Networks
CALHN, SALHN, NALHN, CHSALHN, WCHN

Staff impact All Clinical, Medical, Nursing, Allied Health, Emergency, Dental, Mental Health, Pathology

PDS reference CG104

Version control and change history

Version	Date from	Date to	Amendment
1.0	May 2013	October 2013	Original version
2.0	October 2013	March 2017	Review; Dosing changes
3.0	07 March 2017	Current	Review & update

© Department for Health and Ageing, Government of South Australia. All rights reserved.



fluconazole

2mg/mL injection, 10mg/mL oral mixture

© Department of Health, Government of South Australia. All rights reserved

Note

This guideline provides advice of a general nature. This statewide guideline 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.

SA Health does not accept responsibility for the quality or accuracy of material on websites linked from this site and does not sponsor, approve or endorse materials on such links.

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

25 mg/kg loading dose then 12 mg/kg/dose at the frequency listed in table below

Gestational Age (weeks)	Postnatal age (days)	Frequency (hours)
≤ 29	0 to 14	every 48 hours
	>14	every 24 hours
30 to 44	0 to 7	every 48 hours
	>7	every 24 hours

ISBN number:
Endorsed by:
Last Revised:
Contact:

978-1-74243-396-7
South Australian Maternal, Neonatal & Gynaecology Community of Practice
06/03/2017
South Australian Neonatal Medication Guidelines Workgroup at:
NeoMed@health.sa.gov.au

fluconazole

2mg/mL injection, 10mg/mL oral mixture

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 1000-1500g 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 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

To be administered as an infusion 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%

ISBN number:
Endorsed by:
Last Revised:
Contact:

978-1-74243-396-7
 South Australian Maternal, Neonatal & Gynaecology Community of Practice
 06/03/2017
 South Australian Neonatal Medication Guidelines Workgroup at:
 NeoMed@health.sa.gov.au

fluconazole

2mg/mL injection, 10mg/mL oral mixture

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

- > Consider the higher doses for treating severe infections or *Candida* strains with higher MICs (4 to 8 mcg/mL)
- > The higher loading and maintenance doses are based on recent pharmacokinetic/pharmacodynamic data but have not been prospectively tested for efficacy or safety.
- > 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
- > Fluconazole has good tissue penetration, including penetration into the CNS
- > May increase phenytoin levels while the effectiveness may be reduced by rifampicin
- > Dose adjustment (extending dosage interval) may be required if the neonate has poor renal or hepatic function.
- > May increase midazolam levels

ISBN number:
Endorsed by:
Last Revised:
Contact:

978-1-74243-396-7
 South Australian Maternal, Neonatal & Gynaecology Community of Practice
 06/03/2017
 South Australian Neonatal Medication Guidelines Workgroup at:
 NeoMed@health.sa.gov.au

fluconazole

2mg/mL injection, 10mg/mL oral mixture

References

1. Long S, Stevenson D. Reducing Candida infections during neonatal intensive care: management choices, infection control. [http://www.jpeds.com/article/S0022-3476\(05\)00341-0/abstractand fluconazoleprophylaxis.J.Pediatrics](http://www.jpeds.com/article/S0022-3476(05)00341-0/abstractand%20fluconazoleprophylaxis.J.Pediatrics) 2005; 147: 135-41.
2. Wade KC, Benjamin DK. Fluconazole dosing for prevention of treatment of invasive candidiasis in young infants. *Pediatr Infec Dis journal* 2009; 28: 717-723.
3. Kaufman D. Getting to Zero. Preventing invasive Candida infections and eliminating infection-related mortality and morbidity in extremely preterm infants. *Early Human Development* 8852; 2012: s45-s49.

Version control and change history**PDS reference:** OCE use only

Version	Date from	Date to	Amendment
1.0	May 2013	October 2013	Original version
2.0	October 2013	March 2017	Review; Dosing changes
3.0	March 2017	Current	Review and update

ISBN number:
Endorsed by:
Last Revised:
Contact:

978-1-74243-396-7
 South Australian Maternal, Neonatal & Gynaecology Community of Practice
 06/03/2017
 South Australian Neonatal Medication Guidelines Workgroup at:
 NeoMed@health.sa.gov.au