

South Australian Neonatal Medication Guidelines

ursodeoxycholic Acid

50mg/mL oral mixture

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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.

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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

Synonyms

Ursodiol

Dose and Indications

Treatment of neonatal cholestasis

Oral

10mg/kg every twelve hours

Dose may be increased up to 15mg/kg every twelve hours.

Preparation and Administration

Oral

The oral mixture contains 50mg/mL ursodeoxycholic acid.

Dose	5mg	10mg	15mg	20mg	25mg	30mg
Volume	0.1mL	0.2mL	0.3mL	0.4mL	0.5mL	0.6mL

Administer with feeds.



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Adverse Effects

Common

Diarrhoea

Infrequent

Increased cholestasis, vomiting, abdominal pain

Monitoring

- > Liver function tests

Practice Points

- > It is important to prevent fat-soluble vitamin deficiency where there is cholestasis. Vitamin K deficiency, in particular can cause potentially lethal intracranial bleeding.

References

- > Chen CY, Tsao PN, Chen HL, Chou HC, Hsieh WS, Chang MH. Ursodeoxycholic acid (UDCA) therapy in very-low-birth-weight infants with parenteral nutrition-associated cholestasis. *The Journal of Pediatrics*. 2004 Sep 1;145(3):317-21

Document Ownership & History

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Approval Date	Version	Who approved New/Revised Version	Reason for Change
5/7/18	V2	SA Health Safety and Quality Strategic Governance Committee	Formally reviewed in line with 5 year scheduled timeline for review.
11/2012	V1	SA Maternal & Neonatal Clinical Network	Original SA Maternal & Neonatal Clinical Network approved version.

