

Ibuprofen

10 mg/2 mL injection

100 mg/5 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

Dose and Indications

For Treatment of Haemodynamically Significant Patent Ductus Arteriosus (PDA)

> Intravenous, Oral:

- Three-day course of therapy, doses to be given 24 hours apart

	Dose 1	Dose 2	Dose 3
Standard dose	10 mg/kg/dose	5 mg/kg/dose	5 mg/kg/dose
High dose*	20 mg/kg/dose	10 mg/kg/dose	10 mg/kg/dose

**High dose may be considered in babies greater than 72 hours of age, where renal function is sufficient.*

- A full course of ibuprofen may not be necessary if ductal constriction or closure is demonstrated.
- Oral mixture can be used if the neonate is tolerating enteral feeds.
- If the ductus arteriosus remains patent and haemodynamically significant a further course may be given.



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Preparation and Administration**Intravenous**

- > The intravenous injection 10 mg/2 mL contains 5 mg/mL ibuprofen.

Ibuprofen 5 mg/mL (intravenous)

Dose	2.5 mg	5 mg	7.5 mg	10 mg	12.5 mg	15 mg	20 mg
Volume	0.5 mL	1 mL	1.5 mL	2 mL	2.5 mL	3 mL	4 mL

- > Administer as an intravenous infusion over at least 15 minutes. Avoid extravasation.

Oral

- > The oral mixture 100 mg/5 mL contains 20 mg/mL ibuprofen.

Ibuprofen 20 mg/mL (oral)

Dose	3 mg	6 mg	9 mg	12 mg	15 mg
Volume	0.15 mL	0.3 mL	0.45 mL	0.6 mL	0.75 mL

- > Give with feeds to minimise gastrointestinal irritation.

Compatible Fluids

Sodium chloride 0.9%, glucose 5%

Adverse Effects

- > Transient renal impairment (especially in states with poor renal perfusion), impaired platelet function, thrombocytopenia, salt and fluid retention, hypertension, gastrointestinal perforation (particularly if used concurrently or in close proximity to corticosteroid administration), hyperkalaemia, bleeding (particularly gastrointestinal), neutropenia, blood dyscrasias, interstitial nephritis, hepatitis.
- > Ibuprofen has been shown to displace bilirubin from its binding site to albumin; hence it may cause an increase in unbound bilirubin in those infants with a high unconjugated bilirubin.

Monitoring

- > Assess for ductal closure
- > Serum creatinine, BUN and platelet count should be obtained prior to commencing treatment
- > Renal function, urine output and regular blood gases
- > Weight (where clinical state allows)
- > Assess for signs of bleeding and platelet dysfunction



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Practice Points

- > If anuria or oliguria occurs after any dose, further dosing should be reviewed.
- > **Absolute contraindications:**
 - congenital heart disease with a duct-dependent pulmonary or systemic circulation
 - NEC (proven or suspected).
- > **Relative contraindications:**
 - thrombocytopenia and/or coagulopathy
 - active bleeding
 - acute infection
 - acute renal impairment
 - pulmonary hypertension.
- > Use with caution in hepatic disease and concomitant use of nephrotoxic drugs (e.g. vancomycin, gentamicin, furosemide).
- > Ibuprofen may decrease clearance of aminoglycosides. Strict surveillance of aminoglycoside serum levels is recommended in those babies who have both ibuprofen and aminoglycosides prescribed.
- > Ibuprofen is a better tolerated medication than indomethacin. There is less effect on renal and gastrointestinal function.
- > Before administration of ibuprofen an echocardiographic examination is strongly recommended to exclude duct dependent congenital heart disease.

References

- Dani C, Vangi V, Bertini G, Pratesi S, Lori I, Favelli F et al. High-Dose Ibuprofen for Patent Ductus Arteriosus in Extremely Preterm Infants: A Randomized Controlled Study. *Clinical Pharmacology & Therapeutics* 2012; 91(4) 590-596
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- Ohlsson, 2020, Ibuprofen for the treatment of patent ductus arteriosus in preterm or low birth weight (or both) infants (Review), *Cochrane Database of Systematic Reviews*, The Cochran Collaboration, Issue 2



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Suggested citation:

Neonatal Community of Practice. Ibuprofen [Internet]. South Australian Neonatal Medication Guideline. SA Health, Government of South Australia. 2025. 4.1p. Guideline No.:NMG071. Available from: <http://www.sahealth.sa.gov.au/neonatal>.

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Document Ownership & History

Developed by: SA Maternal, Neonatal & Gynaecology Strategic Executive Leadership Committee

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Approved by: Clinical Guidelines Domain Custodian

Next review due: 21/05/2030

CGSQ number: **NMG071**

Guideline history: Is this a new Neonatal Medication Guideline (V1)? **N**
 Does this Neonatal Medication Guideline amend or update and existing Neonatal Medication Guideline? **Y**
 If so, which version? **4.0**
 Does this Neonatal Medication Guideline replace another Neonatal Medication Guideline with a different title? **N**
 If so, which Neonatal Medication Guideline (title)?

Approval Date	Version	Who approved New/Revised Version	Reason for Change
12/07/2025	V4.1	Clinical Guideline Domain Custodian	Formatting updated and no change to content
21/05/2025	V4	Clinical Guideline Domain Custodian	Formal review
28/4/2017	V3	SA Health Safety and Quality Strategic Governance Committee	Change to ibuprofen formulation, review of document
3/2014	V2	SA Health Safety and Quality Strategic Governance Committee	Change in ibuprofen formulation, change to dosing
11/2012	V1	SA Maternal & Neonatal Clinical Network	Original SA Maternal & Neonatal Clinical Network approved version.

