Indometacin

1mg injection

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

Indometacin

Dose and Indications

Treatment of significant patent ductus arteriosus (PDA)

Intravenous

Age at 1st Dose	1st Dose	2nd dose (To be administered 12 - 24 hours **after first dose**)	3rd dose (To be administered 12 - 24 hours **after second dose**)
< 48 hours	0.2mg/kg	0.1mg/kg	0.1mg/kg
> 48 hours	0.2mg/kg	0.2mg/kg	0.2mg/kg

If the ductus arteriosus does not close 48 hours after the last dose or if it re-opens, a second course, as above may be given.

PLEASE NOTE: Babies less than 1kg may require a dose <u>less than 0.1mg</u>. Please ensure you double check the dose calculation.

Preparation and Administration

Intravenous

Add 2mL of water for injection to the vial (1mg) and shake gently to dissolve. The resulting solution contains 0.5mg/mL indometacin.

Example calculations:

Dose	0.05mg	0.1mg	0.2mg	0.3mg	0.4mg	0.5mg
Volume	0.1mL	0.2mL	0.4mL	0.6mL	0.8mL	1mL

Administer as an intravenous infusion over 20 to 30 minutes.

Compatible Fluids

Water for Injection, Sodium chloride 0.9%

Further dilution is not recommended. Indometacin Agila is not buffered and reconstitution with solutions at pH values below 6 may result in precipitation of the insoluble indometacin free acid moiety. It cannot be run with parenteral nutrition solutions as they usually have a pH between 4-5.

Adverse Effects

Common

Gastrointestinal perforation (particularly if used concurrently or in close proximity to corticosteroids), bleeding, salt and fluid retention, hypertension

Infrequent

Hyperkalaemia, renal impairment, rash

Rare

Blood dyscrasias, interstitial nephritis, acute renal failure, hepatitis

Monitoring

- Assess for ductal closure
- Renal function and urine output
- Serum electrolytes, Blood Urea Nitrogen (BUN) and glucose
- Assess for signs of bleeding

Practice Points

- Slow administration is essential to prevent reduction to organ blood flow
- If anuria or oliguria occurs after any dose, further dosing should be reviewed
- Indometacin is contraindicated in babies with active bleeding, severe thrombocytopenia and bleeding disorders, known or suspected NEC, congenital heart disease with ductal-dependant systemic blood flow or renal failure
- Indometacin solution should be prepared only with 2 ml of preservative free sterile sodium chloride injection or water for injection. Preparations containing glucose must not be used.
- Use with caution in known infection
- Indometacin may decrease clearance of aminoglycosides. Hence strict surveillance of aminoglycoside serum levels is recommended in those babies who have both indometacin and aminoglycosides prescribed
- Before administration of indometacin, an echocardiographic examination should generally be performed in order to detect a haemodynamically significant patent ductus arteriosus and to exclude pulmonary hypertension and duct-dependent congenital heart disease

References

- Herrera CM, Holberton JR, Davis PG. Prolonged versus short course of indometacin for the treatment of patent ductus arteriosus in preterm infants. Cochrane Database of Systematic Reviews 2007, Issue 2. Art. No.: CD003480. DOI: 10.1002/14651858.CD003480.pub3.
- Kluckow M, Jeffery M, Gill A, Evans N. A randomised placebo-controlled trial of early treatment of the patent ductus arteriosus. Archives of Disease in Childhood-Fetal and Neonatal Edition. 2013 Dec 6:fetalneonatal-2013.

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