

sildenafil

2mg/mL oral mixture*, 10mg/12.5mL injection

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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

Treatment of persistent pulmonary hypertension

Intravenous

Loading dose of 0.4mg/kg over 3 hours followed by a continuous infusion of 0.07mg/kg/hour

Oral

0.5mg/kg every 8 to 12 hours, increasing according to response to a maximum of 3mg/kg every 6 hours.



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Preparation and Administration

Intravenous

Select the strength required based on the weight of the infant in the context of any fluid restrictions. Sildenafil Concentration Selection Tables can be found on the following pages of this guideline to assist prescribers to gauge which strength is best for the patient.

There are **TWO STEPS** to this process.

STEP ONE: Dilute 12.5mL (10mg) of sildenafil injection with 7.5mL of 5% glucose (to a final volume of 20mL). This results in a 0.5mg/mL solution.

STEP TWO: Dilute the appropriate volume of the 0.5mg/mL sildenafil solution using 5% glucose; and administer by continuous infusion. Diluted preparation is stable for 24 hours at room temperature.

The three standard concentrations to select from are:

- > Sildenafil 0.1mg/mL
- > Sildenafil 0.2mg/mL
- > Sildenafil 0.4mg/mL

Formulae

To calculate infusion rate (mL/hr):

$$\text{Rate (mL/hr)} = \frac{\text{dose (milligrams/kg/hour)} \times \text{weight (kg)}}{\text{Strength (milligrams/mL)}}$$

To calculate the dose (milligrams/kg/hour):

$$\text{Dose (milligrams/kg/hour)} = \frac{\text{Rate (mL/hr)} \times \text{Strength (milligrams/mL)}}{\text{weight (kg)}}$$

Compatible Fluids

Glucose 5%



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Sildenafil Concentration Selection Table for **25mL** syringes

Sildenafil 0.1mg/mL

STEP ONE: Dilute 12.5mL (10mg) of sildenafil injection with 7.5mL of 5% glucose (to a final volume of 20mL). This results in a 0.5mg/mL solution.

STEP TWO: Dilute 5mL sildenafil (0.5mg/mL) with 20mL of 5% glucose (total of 25mL). The resulting solution contains 0.1mg/mL Sildenafil.

Rate (mL/hr)	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1	Rate (mL/hr)
Weight (kg)	Approximate mg/kg/hr									Weight (kg)
1.5	0.01	0.02	0.03	0.03	0.04	0.05	0.05	0.06	0.07	1.5
2	0.01	0.02	0.02	0.03	0.03	0.04	0.04	0.05	0.05	2
2.5	0.01	0.01	0.02	0.02	0.02	0.03	0.03	0.04	0.04	2.5
3		0.01	0.01	0.02	0.02	0.02	0.03	0.03	0.03	3
3.5			0.01	0.01	0.02	0.02	0.02	0.03	0.03	3.5
4				0.01	0.02	0.02	0.02	0.02	0.03	4
4.5					0.01	0.02	0.02	0.02	0.02	4.5
5					0.01	0.01	0.02	0.02	0.02	5

Discard remaining solution.

Sildenafil 0.2mg/mL

STEP ONE: Dilute 12.5mL (10mg) of sildenafil injection with 7.5mL of 5% glucose (to a final volume of 20mL). This results in a 0.5mg/mL solution.

STEP TWO: Dilute 10mL sildenafil (0.5mg/mL) with 15mL of 5% glucose (total of 25mL). The resulting solution contains 0.2mg/mL sildenafil.

Rate (mL/hr)	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1	Rate (mL/hr)
Weight (kg)	Approximate mg/kg/hr									Weight (kg)
1.5	0.03	0.04	0.05	0.07	0.08	0.09	0.11	0.12	0.13	1.5
2	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09	0.10	2
2.5	0.02	0.02	0.03	0.04	0.05	0.06	0.06	0.07	0.08	2.5
3	0.01	0.02	0.03	0.03	0.04	0.05	0.05	0.06	0.07	3
3.5	0.01	0.02	0.02	0.03	0.03	0.04	0.05	0.05	0.06	3.5
4		0.02	0.02	0.03	0.03	0.04	0.04	0.05	0.05	4
4.5		0.01	0.02	0.02	0.03	0.03	0.04	0.04	0.04	4.5
5		0.01	0.02	0.02	0.02	0.03	0.03	0.04	0.04	5

Discard remaining solution

Sildenafil 0.4mg/mL

STEP ONE: Dilute 12.5mL (10mg) of sildenafil injection with 7.5mL of 5% glucose (to a final volume of 20mL). This results in a 0.5mg/mL solution.

STEP TWO: Dilute 20mL sildenafil (0.5mg/mL) with 5mL of 5% glucose (total of 25mL). The resulting solution contains 0.4mg/mL sildenafil.

Rate (mL/hr)	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1	Rate (mL/hr)
Weight (kg)	Approximate mg/kg/hr									Weight (kg)
1.5	0.05	0.08	0.11	0.13	0.16	0.19	0.21	0.24	0.27	1.5
2	0.04	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20	2
2.5	0.03	0.05	0.06	0.08	0.10	0.11	0.13	0.14	0.16	2.5
3	0.03	0.04	0.05	0.07	0.08	0.09	0.11	0.12	0.13	3
3.5	0.02	0.03	0.05	0.06	0.07	0.08	0.09	0.10	0.11	3.5
4	0.02	0.03	0.04	0.05	0.06	0.07	0.08	0.09	0.10	4
4.5		0.03	0.04	0.04	0.05	0.06	0.07	0.08	0.09	4.5
5		0.02	0.03	0.04	0.05	0.06	0.06	0.07	0.08	5

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Discard remaining solution

Oral

The oral mixture contains 2mg/mL sildenafil

Dose	0.2mg	0.4mg	0.6mg	0.8mg	1mg	1.2mg	1.4mg	1.6mg
Volume	0.1mL	0.2mL	0.3mL	0.4mL	0.5mL	0.6mL	0.7mL	0.8mL

* The 2mg/mL oral mixture is not commercially available however is manufactured at Women's & Children's Health Network Pharmacy and Flinders Medical Centre Pharmacy.

Adverse Effects

Common

Hypotension, dyspepsia, flushing, headache, nasal congestion, worsening oxygenation

Monitoring

> Continuous monitoring of blood pressure and oxygen

Practice Points

- > Pharmacokinetics of sildenafil in neonates is highly variable
- > Drug interactions: CYP3A4 enzyme inhibitors such as rifampicin decrease levels of sildenafil.
- > Concomitant administration with other antihypertensive agents may result in excessive hypotension.
- > Consider reduced doses in context of renal failure
- > Care should be taken when stopping sildenafil. Weaning of the dose should be considered.

References

1. Steinhorn RH et al. Intravenous sildenafil in the treatment of neonates with persistent pulmonary hypertension, *J Paeds*, 2009, 155 (6), pp 841 – 847
2. Al Hadithy et al. Stability of sildenafil (Revatio®) dilutions in dextrose 5%, *Intensive care med*, 2011, 37, pp 1899



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