		Type: Drug Guideline	Document reference: 2962	Manual Classification: Waikato DHB Drug Guidelines
Title: Sildenafil for neonates			Effective date: 30 March 2022	
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BRIEF ADMINISTRATION GUIDE

For detailed information refer to [The Australasian Neonatal Medicines Formulary sildenafil guideline](#)



Critical Note: there are minor variations between the ANMF and Waikato DHB best practice within this drug guideline – see **yellow shaded text**

- Indications:**
- Persistent pulmonary hypertension
 - To facilitate weaning from inhaled nitric oxide

Route: Intravenous or oral

- Injection supplied as sildenafil 10 mg/12.5 mL (0.8 mg/mL) vial
An unapproved medicine, available under Section 29 of the Medicines Act
- Oral supplied as sildenafil 2 mg/ml oral suspension (manufactured by pharmacy)

Dose: Intravenous Infusion

- Loading dose: 400 microgram/kg administered over 3 hours, followed by
- Maintenance dose: 67 microgram/kg/hr for up to 7 days

Oral

- Initially 0.5 – 1 mg/kg/dose every 6 hours, then titrate to 2 mg/kg/dose according to response
- May increase to a maximum of 3 mg/kg/dose every 6 hours

Preparation and administration

Compatible fluids: sodium chloride 0.9%, glucose 5%

Intravenous Infusion

- Select the **concentration** of sildenafil required based on the weight of the infant and in the context of any fluid restrictions (refer to appendix for assistance) and dilute the appropriate volume of sildenafil injection using compatible fluid in accordance with the table below:


Final Sildenafil Concentration	300 microgram/mL	800 microgram/mL
Volume of sildenafil (10 mg/12.5mL)	12.5 mL	12.5 mL
Volume of compatible fluid	20.8 mL	0 mL
Total volume for infusion	33.3 mL	12.5 mL

- Administer the loading dose over **3 hours** (rate 133 microgram/kg/hr)
- Continue with the maintenance dose at a rate of 67 microgram/kg/hr for up to 7 days

$$\text{Rate (mL/hr)} = \frac{\text{Dose (microgram/kg/hour)} \times \text{Weight (kg)}}{\text{Concentration (microgram/mL)}}$$

Oral

- Shake suspension well prior to use
- Draw up prescribed dose in an oral syringe and administer orally or via oro-gastric tube, preferably with feed to minimise risk of gastrointestinal irritation

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Monitoring

- Continuous monitoring of blood pressure, heart rate and oxygenation

Storage and Stability

- Prepare a new IV infusion solution every 24 hours
- Store oral solution in the fridge (preferable) and discard according to expiry date on bottle (usually one month from manufacture)

Guardrails Information

Sildenafil will be Guardrail profiled on the CC pump for NICU. Following are the guardrail limits:


Guardrails Drug Name	Sildenafil (Load)*	Sildenafil (Maint)
Concentration (mcg/ml)		
Minimum	200	200
Maximum	800	800
Dose rate (mcg/kg/hour)		
Default	133	67
Soft minimum	131	65
Soft maximum	134	67
Hard max	134	68

References

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Appendix

Infusion tables to assist concentration selection

Table 1: Infusion rates when using sildenafil concentration **300 microgram/mL**
(most useful for neonates < 3 kg)

Rate (mL/hr)	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1
Weight (kg)	Approximate micrograms/kg/hour									
0.5	60	120	180	240	300	360	420	480	540	600
1	30	60	90	120	150	180	210	240	270	300
1.5	20	40	60	80	100	120	140	160	180	200
2	15	30	45	60	75	90	105	120	135	150
2.5	12	24	36	48	60	72	84	96	108	120
3	10	20	30	40	50	60	70	80	90	100
3.5	9	17	26	34	43	51	60	69	77	86
4	8	15	23	30	38	45	53	60	68	75
4.5	7	13	20	27	33	40	47	53	60	67
5	6	12	18	24	30	36	42	48	54	60

Table 2: Infusion rates when using sildenafil concentration **800 microgram/mL**
(most useful for neonates \geq 3 kg)

Rate (mL/hr)	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1
Weight (kg)	Approximate micrograms/kg/hour									
1	80	160	240	320	400	480	560	640	720	800
1.5	53	107	160	213	267	320	373	427	480	533
2	40	80	120	160	200	240	280	320	360	400
2.5	32	64	96	128	160	192	224	256	288	320
3	27	53	80	107	133	160	187	213	240	267
3.5	23	46	69	91	114	137	160	183	206	229
4	20	40	60	80	100	120	140	160	180	200
4.5	18	36	53	71	89	107	124	142	160	178
5	16	32	48	64	80	96	112	128	144	160