

# SILDENAFIL

<b>Indication</b>	<ul style="list-style-type: none"> <li>Chronic pulmonary hypertension<sup>1-3</sup></li> <li>Acute pulmonary hypertension refractory to iNO or infant unable to be weaned from iNO<sup>1,3,4</sup></li> </ul>
<b>ORAL</b>	<b>Presentation</b> <ul style="list-style-type: none"> <li>Oral solution: 2 mg in 1 mL               <ul style="list-style-type: none"> <li>Available: Central Pharmacy QH   Mater Pharmacy Production Services</li> </ul> </li> <li>Tablet: 20 mg</li> </ul>
	<b>Dosage</b> <sup>4,5</sup> <ul style="list-style-type: none"> <li>0.5 mg/kg every 8 hours               <ul style="list-style-type: none"> <li>If required, increase to 1 mg/kg every 8 hours</li> <li>Maximum dose 2 mg/kg every 8 hours</li> </ul> </li> </ul>
	<b>Preparation</b> (oral solution) <ul style="list-style-type: none"> <li>Shake well</li> <li>No dilution required</li> </ul>
	<b>Preparation</b> (tablet if oral solution not available) <ul style="list-style-type: none"> <li>Add one tablet to 10 mL water for injection</li> <li>Shake well until dissolved (may take several minutes)               <ul style="list-style-type: none"> <li>Concentration now equal to 2 mg/mL</li> </ul> </li> </ul>
	<b>Administration</b> <ul style="list-style-type: none"> <li>Draw up prescribed dose in oral/enteral syringe and administer immediately</li> <li>Oral/OGT/NGT after feeds</li> </ul>
<b>Special considerations</b>	<ul style="list-style-type: none"> <li>Consult with paediatric cardiologist prior to initiation and for dose increments/variation</li> <li>ELBW infants               <ul style="list-style-type: none"> <li>Ensure retinal vascularisation is established prior to use<sup>4</sup></li> </ul> </li> <li>Caution if sepsis<sup>4</sup></li> <li>Not recommended               <ul style="list-style-type: none"> <li>If left ventricular outflow obstruction (e.g. aortic stenosis, idiopathic hypertrophic subaortic stenosis) or pulmonary veno-occlusive disease<sup>4</sup></li> <li>Long term use with pulmonary arterial hypertension (due to a dose-related increased risk of mortality)<sup>4,6</sup></li> <li>Abrupt cessation (due to risk of clinical deterioration), wean dose prior to ceasing<sup>5,6</sup></li> </ul> </li> </ul>
<b>Monitoring</b>	<ul style="list-style-type: none"> <li>ECHO               <ul style="list-style-type: none"> <li>Prior to commencement<sup>1,3</sup></li> </ul> </li> <li>Continuous (at initiation of treatment and for each dose adjustment)               <ul style="list-style-type: none"> <li>Oxygen saturation<sup>4</sup></li> <li>BP<sup>4</sup></li> </ul> </li> <li>If IABP not available, use NIBP               <ul style="list-style-type: none"> <li>Before administration (baseline)</li> <li>After first dose, every 15 minutes for 2 hours</li> <li>Pre and post dose for 48 hours after commencement, then if stable, cease</li> <li>Resume monitoring with dose adjustment</li> </ul> </li> <li>Severe renal/hepatic impairment<sup>5</sup> <ul style="list-style-type: none"> <li>Weekly function testing (at SMO discretion) as may require dose adjustment</li> </ul> </li> </ul>
<b>Compatibility</b>	<ul style="list-style-type: none"> <li>Not applicable</li> </ul>
<b>Incompatibility</b>	<ul style="list-style-type: none"> <li>Not applicable</li> </ul>
<b>Interactions</b>	<ul style="list-style-type: none"> <li>Increased risk of severe hypotension               <ul style="list-style-type: none"> <li>Contraindicated: nitrates: glyceryl trinitrate<sup>4,7</sup>, isosorbide salts<sup>4,7</sup>, sodium nitroprusside<sup>4,7</sup>, organic nitrates in any form<sup>4,6,7</sup></li> <li>Caution: antihypertensives<sup>4</sup>, vasodilators<sup>4</sup></li> </ul> </li> <li>Increased sildenafil exposure and associated side effects               <ul style="list-style-type: none"> <li>HIV antiviral therapies (e.g. HIV protease inhibitors)<sup>4</sup></li> <li>Azole antifungals—voriconazole<sup>4</sup>, fluconazole<sup>4,5</sup>, posaconazole<sup>4,5</sup></li> <li>Erythromycin<sup>7</sup>, clarithromycin<sup>7</sup></li> </ul> </li> <li>Decreased sildenafil exposure and effect               <ul style="list-style-type: none"> <li>Rifampicin<sup>7</sup>, phenytoin<sup>7</sup>, carbamazepine<sup>7</sup></li> </ul> </li> </ul>



<b>Stability</b>	<ul style="list-style-type: none"> <li>• Oral solution <ul style="list-style-type: none"> <li>◦ Refrigerate 2–8 °C<sup>8</sup></li> <li>◦ Discard 4 weeks after opening or as per local policy</li> </ul> </li> <li>• Tablet <ul style="list-style-type: none"> <li>◦ Store below 25 °C<sup>9</sup></li> </ul> </li> </ul>
<b>Side effects</b>	<ul style="list-style-type: none"> <li>• Circulatory: hypotension<sup>4,5</sup>, deterioration in oxygenation<sup>4</sup></li> <li>• Digestive: hematemesis<sup>10</sup>, melena<sup>10</sup>, abdominal distension<sup>10</sup>, diarrhea<sup>5,11</sup>, vomiting<sup>5,10,11</sup></li> <li>• Ophthalmic: worsening retinopathy of prematurity<sup>4,5</sup></li> </ul>
<b>Actions</b>	<ul style="list-style-type: none"> <li>• Onset of action approximately 1 hour<sup>4</sup></li> <li>• Half-life approximately 2–3 hours<sup>4</sup></li> <li>• PDE5 inhibitor<sup>1,3,4,6</sup></li> <li>• Prevents PDE5 from degrading cGMP<sup>4,10</sup>, therefore: <ul style="list-style-type: none"> <li>◦ Increases cGMP level in pulmonary arterial smooth muscle cells<sup>1,3,4</sup></li> <li>◦ Relaxes smooth muscle in the pulmonary vascular bed<sup>3,4,6,11</sup></li> <li>◦ Enhances nitric oxide mediated vasodilation<sup>6,10</sup></li> <li>◦ Reduces pulmonary vascular resistance<sup>1,4,6</sup></li> </ul> </li> </ul>
<b>Abbreviations</b>	BP: blood pressure, cGMP: cyclic guanosine monophosphate, ECHO: echocardiogram, ELBW: extremely low birth weight, HIV: human immunodeficiency virus, IABP: intra-arterial blood pressure, iNO: inhaled nitric oxide, NGT: nasogastric tube, NIBP: non-invasive blood pressure, OGT: orogastric tube, PDE5: phosphodiesterase type 5, SMO: most senior medical officer
<b>Keywords</b>	blood pressure, neonatal medicine, neonatal monograph, nitric oxide, PDE5, pulmonary hypertension, sildenafil, vasodilator, Viagra®

The Queensland Clinical Guideline *Neonatal Medicines* is integral to and should be read in conjunction with this monograph. Refer to the disclaimer. Destroy all printed copies of this monograph after use.

## References

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## Document history

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