SILDENAFIL This drug must be guardrailed

<table>
<tr><td>Trade Name</td><td>Avigra ®, Viagra® (Pfizer) Vedafil® (Viatris)</td></tr>
<tr><td>Class</td><td>Phosphodiesterase Inhibitor</td></tr>
<tr><td>Mechanism of Action</td><td>Sildenafil is a potent and selective inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type 5 (PDE5). Inhibition of PDE5 increases cellular levels of cGMP, promoting relaxation of vascular smooth muscle particularly in the lungs where PDE5 is found in high concentrations.</td></tr>
<tr><td>Indications</td><td>Persistent Pulmonary Hypertension of the Newborn
Weaning from Nitric oxide therapy
Hypertension following cardiac surgery</td></tr>
<tr><td>Contraindications</td><td>Concurrent treatment with nitrates (eg glyceryl trinitrate)
Family history of hereditary degenerative retinal disorders</td></tr>
<tr><td>Supplied As</td><td>IV: 10mg/12.5mL = 0.8mg/mL
Oral: 2mg/mL solution to be made up by Pharmacy using 50mg tablets and oraplus/orasweet.
After hours when no pre-made solution available – see section below</td></tr>
<tr><td>Dilution</td><td>IV: Single Strength
<table>
<tr><th>Drug</th><th>5% Glucose Added</th><th>Final Volume</th><th>Concentration</th></tr>
<tr><td>10mg
12.5mL</td><td>37.5mL</td><td>50mL</td><td>0.2 mg/mL</td></tr>
</table>
IV: Double Strength
<table>
<tr><th>Drug</th><th>5% Glucose Added</th><th>Final Volume</th><th>Concentration</th></tr>
<tr><td>10mg
12.5mL</td><td>12.5mL</td><td>25mL</td><td>0.4 mg/mL</td></tr>
</table>
Oral: No dilution required if pre-prepared solution is available. But, for emergency after hours use, 50mg tablets are kept in the Level 3 controlled drug cupboard and can be dispersed in 25mL water to make a 2mg/mL solution</td></tr>
<tr><td>Dosage

Must chart guardrail and use Alaris pump</td><td>IV: Loading dose 0.4mg/kg over 3 hours
Maintenance dose 0.07mg/kg/hr continuous infusion

Oral: Start at 0.5 mg/kg/dose and can increase to 1mg/kg/dose
Maximum of 2mg/kg/dose
Wean the dose prior to stopping by altering the interval and/or reducing the dose gradually</td></tr>
</table>

Guardrail	Conc: Min – 0.2mg/mL Max - 0.4mg/mL Soft Min: 0.02 mg/kg/hr Hard Max: 0.14 mg/kg/hr Soft Max: 0.07 mg/kg/hr Default: 0.07 mg/kg/hr
Interval	**IV:** Continuous infusion **Oral:** 6 - 8 hourly
Administration	Continuous iv infusion Oral/NG tube
Compatible With	**Solution:** 5% glucose. (not tested in any other IV solution) No other data on compatibility with other IV solutions (including TPN) or medicines are available. **Terminal Y-site:** Adrenaline, alprostadil, amphotericin B liposomal. caffeine citrate,cefotaxime,ciprofloxacin, dexmedetomidine, dobutamine, dopamine, fentanyl, fluconazole, gentamicin, insulin, levetiracetam, linezolid, SMOF lipid, metronidazole, midazolam, milrinone, morphine, noradrenaline, paracetamol, pentoxifylline, piperacillin tazobactam, vancomycin, vasopressin, vecuronium. Variable compatibility with acyclovir, amoxicillin, calcium gluconate, hydrocortisone succinate, indomethacin, phenobarbital, rifampicin use a separate line if possible Do not mix with other oral medications
Incompatible With	Amphotericin B, flucloxacillin, furosemide, heparin, ibuprofen, meropenem, sodium bicarbonate No data on other medicines available
Interactions	Medications that inhibit CYP3A4 eg ciprofloxacin, erythromycin, fluconazole, itraconazole and ketoconazole will increase sildenafil plasma concentrations. Enzyme inducers eg phenobarbitone, phenytoin may decrease sildenafil plasma concentrations.
Monitoring	Blood pressure Echocardiogram review of pulmonary hypertension after starting treatment and at least fortnightly thereafter.
Stability	**IV:** Single use vial only, discard after opening **Oral:** If solution is prepared in NICU using tablets give dose immediately after preparation and discard remaining solution.
Storage	Store vials at room temperature Pharmacy prepared suspension is stable for 30 days in the fridge.

Adverse Reactions	Headache, flushing, dyspepsia, nasal stuffiness, penile erection, raised intraocular pressure, rare hypersensitivity reactions
Metabolism	Sildenafil is cleared predominantly by the CYP3A4 (major route) and CYP2C9 (minor route) hepatic microsomal isoenzymes. The major circulating metabolite results from N-demethylation of sildenafil. This metabolite has a PDE selectivity profile similar to sildenafil and an in-vitro potency for PDE5 approximately 40% of the parent drug. Excretion is predominantly via faeces (approx 80%)
Comments	IV sildenafil is approved by Pharmac for treatment of neonates with PPHN and/or congenital diaphragmatic hernia. One of these indications is required on the prescription chart to ensure that MOH requirements are fulfilled in case of audit.. Oral mixture is now subsidised by Pharmac for community supply but requires a special authority number to be completed
References	1. Paediatric BNF 2005 2. www.dial.org.uk 3. www.medsafe.govt.nz 4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 31/08/2026). 5. Neofax in www.micromedexsolutions.com 6. Revatio® Data Sheet (Pfizer) 7. Sem Fetal Neonatal. June 2022. Cookson et al
Updated By	P Schmidt & B Robertshawe September 2006 A Lynn, B Robertshawe October 2009, Aug 2010 A Lynn, B Robertshawe Dec 2012 (re-order profile), A Lynn, B Robertshawe Feb 2013 change to 2mg/mL from 5mg/mL A Lynn, B Robertshawe, N Austin Oct 2017 (iv preparation) A Lynn, B Robertshawe Feb 2022 (update of IV compatibility section and oral brand) A Lynn, B Robertshawe May 2022 (update Pharmac requirements, dosing) A Lynn, B Robertshawe May 2023 (allow double strength conc.) A Lynn, B Robertshawe August 2026 (routine update including compatibility)