



NEONATAL



SILDENAFIL

This document should be read in conjunction with this [DISCLAIMER](#)

Presentation	<p>Ampoule: 10mg/12.5mL (0.8mg/mL) Mixture: 2mg/mL (prepared in KEMH/PCH Pharmacy)</p>
Action & Indication	<p>Sildenafil is a selective pulmonary vasodilator used to treat: Persistent Pulmonary Hypertension of the Neonate (PPHN) where</p> <ul style="list-style-type: none"> • Refractory to inhaled nitric oxide (iNO) and other conventional therapies or; • Neonate persistently unable to be weaned off inhaled nitric oxide or; • Where inhaled nitric oxide and high frequency jet ventilation are not available or contraindicated. <p>Chronic pulmonary hypertension secondary to respiratory, cardiac or chest wall disease.</p> <p>Use in <37 weeks: IV sildenafil is reserved for severe refractory Pulmonary hypertension. Potential risk (pulmonary haemorrhage) should be considered versus overall benefit of therapy.</p>
Precautions	<p>Sildenafil should not be used in patients;</p> <ul style="list-style-type: none"> • with hereditary degenerative retinal disorders. <p>Use with caution in patients;</p> <ul style="list-style-type: none"> • receiving nitrates, • with hypotension (or concurrent use with alprostadil) • suspected or confirmed sepsis • with bleeding disorders • concomitant use of CYP 3A4 inhibitors (e.g. fluconazole)
Dose	<p><u>Pulmonary hypertension</u></p> <p>IV Continuous Infusion:</p> <p><37 Weeks Corrected Gestational Age Loading: 0.1 mg/kg (0.13mg/kg/hour) administered over 45 minutes Maintenance: 0.5 to 1.2mg/kg/day (0.021 to 0.05mg/kg/hour) as a continuous infusion for up to 7 days.</p> <p>≥ 37 Weeks Corrected Gestational Age Loading: 0.4 mg/kg (0.13mg/kg/hour) administered over 3 hours Maintenance: 1.6 mg/kg/day (0.067mg/kg/hour) as a continuous infusion for up to 7 days.</p>

	<p>Oral: Initially 0.25 – 0.5 mg/kg/dose 4 – 8 hourly, adjusted according to response. Maximum dose of 2mg/kg/dose 6 hourly.</p> <p>Patients concurrently receiving other vasodilators (including nitric oxide) should start with a lower dose.</p> <p>May require adjustment in renal or hepatic impairment.</p> <p>Treatment should be weaned gradually to prevent withdrawal.</p>
Monitoring	<p>Oxygen saturation must be continuously monitored when commencing sildenafil as it can acutely increase oxygen requirements due to ventilation/perfusion (V/Q) mismatch.</p> <p>Heart rate, blood pressure, left ventricular performance.</p> <p>Renal and hepatic function.</p> <p>Consider monitoring with echocardiogram.</p>
Preparation / Administration	<p>IV: Compatible Fluid: Glucose 5% (preferred) or Sodium Chloride 0.9%</p> <p><37 Weeks Corrected Gestational Age</p> <p>Dilution Dilute 0.78mL/kg (0.62mg/kg) of sildenafil solution and make to 15mL using compatible fluid.</p> <p>Loading dose: 3.2mL/hour (0.1mg/kg) for 45 minutes</p> <p>Maintenance dose: 0.5 to 1.2mL/hour (0.021 to 0.05mg/kg/hour)</p> <p>>37 Weeks Corrected Gestational Age</p> <p>Dilution Dilute 2.5mL/kg (2mg/kg) of sildenafil solution and make to 15mL using compatible fluid.</p> <p>Loading dose: 1mL/hour (0.4mg/kg) for 3 hours</p> <p>Maintenance dose: 0.5mL/hour (0.067mg/kg/hour)</p> <p>Oral: Use suspension prepared by Pharmacy. May be given at any time with regard to feeds.</p>
Adverse Effect	<p>Common: hypotension, flushing, dyspepsia, headache, dizziness, visual disturbances, nasal congestion, vomiting, rash.</p> <p>Serious: serious cardiovascular disorders (including arrhythmia and sudden cardiac death), raised intra-ocular pressure, swelling of the eyelids.</p>

References	<p>UpTo Date [Accessed 22/06/2017]</p> <p>Paediatric Formulary Committee. BNF for Children: 2012-2013. Pharmaceutical Press; 2012.</p> <p>Steinhorn RH(1), Kinsella JP, Pierce C, Butrous G, Dilleen M, Oakes M, Wessel DL. Intravenous sildenafil in the treatment of neonates with persistent pulmonary hypertension. J Pediatr. 2009 Dec;155(6):841-847</p> <p>Steiner M, Salzer U, Baumgartner S, Waldhoer T, Klebermass-Schrehof K, Wald M, et al. Intravenous sildenafil i.v. as rescue treatment for refractory pulmonary hypertension in extremely preterm infants. Klin Padiatr [Internet]. 2014;226(4):211-5</p> <p>Shah PS, Ohlsson A. Sildenafil for pulmonary hypertension in neonates. Cochrane Database of Systematic Reviews 2011, Issue 8. Art. No.: CD005494. DOI: 10.1002/14651858.CD005494.pub3.</p> <p>Mangum B. Neofax 2012. Thomson Reuters; 2012.</p>
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