HydrALAZINe
Newborn use only

2021

Alert	Intravenous administration can cause unpredictable drop in blood pressure (BP).[1]
Indication	Hypertension[1]
Action	Peripheral vasodilator. Dilatation of arterioles causing decreased systemic vascular resistance.
Drug type	Peripheral vasodilator.
Trade name	Oral: Alphapress IV: Apresoline (preferred), Hydralazine Link (contains propylene glycol - see precautions section).
Presentation	Tablets: 25mg and 50mg Oral solution/suspension prepared by compounding pharmacy (check which strength is stocked with pharmacy). IV: Apresoline powder for injection 20mg ampoule (preferred), Hydralazine Link solution for injection - 20mg/mL vial. Note: IV preparation may be given orally either neat or diluted with water if required.[2]
Dose	**Oral** Starting dose: 0.25 to 1 mg/kg/dose 6-8 hourly.[1,3] Dose may be titrated up to 7.5 mg/kg/day.[1] **IV** Starting dose: 0.15 to 0.6 mg/kg/dose every 4 hours as needed.[1] **Conversion from IV to oral route** Care should be taken when converting IV to oral dosing (1:2 ratio) or oral to IV dosing (2:1 ratio).[4]
Dose adjustment	Therapeutic hypothermia: No information. ECMO: No information. Renal impairment:[14] - If GFR 10 to 50 mL/min/1.73m^2 – Same dose but at 8 hourly interval. - If GFR <10 mL/min/1.73m^2 – Start at lower end and administer 12-24 hourly interval Hepatic impairment: No studies to recommend dose adjustment.
Maximum dose	7.5 mg/kg/day (1)
Total cumulative dose	N/A
Route	IV, Oral
Preparation	**Oral** **For 25 mg tablet:** Disperse ONE tablet in 5 mL of water to make 5 mg/mL. The tablet will disperse within 2 minutes. Shake or stir until an even dispersion is formed and then measure the dose immediately.[2] **For 50 mg tablet:** Disperse ONE tablet in 10 mL of water to make 5 mg/mL. The tablet will disperse within 2 minutes. Shake or stir until an even dispersion is formed and then measure the dose immediately.[2] Solution or suspension: Compounded by pharmacy in-house. No further preparation required. IV hydralazine may be given orally either neat or diluted with water if required. **IV*** **20mL Syringe** Apresoline 20mg powder for injection: Add 1 mL water for injection to the ampoule to make a 20 mg/mL solution. Draw up 0.4 mL (8 mg) of hydralazine and add to 19.6 mL sodium chloride 0.9% to make a final volume of 20mL with a concentration of 0.4 mg/mL.[5] Hydralazine Link solution: Draw up 0.4 mL (8 mg) of hydralazine and add to 19.6 mL sodium chloride 0.9% to make a final volume of 20 mL with a concentration of 0.4 mg/mL.[3,4] **50mL Syringe** Apresoline 20mg powder for injection: Add 1 mL water for injection to the ampoule to make a 20 mg/mL solution. Draw up 1 mL (20 mg) of hydralazine and add to 49 mL sodium chloride 0.9% to make a final volume of 50 mL with a concentration of 0.4 mg/mL.[5] Hydralazine Link solution: Draw up 1 mL (20 mg) of hydralazine and add to 49 mL sodium chloride 0.9% to make a final volume of 50 mL with a concentration of 0.4 mg/mL.[3,4]

	*Hydralazine may react with metals (e.g. filters, needles) to yield discoloured solutions, often yellow or pink. Avoid prolonged contact with metal components; prepare just prior to use.[4]
Administration	Oral: Give with feeds to enhance absorption IV: Inject over 1 to 2 minutes. The maximum rate is 200 microgram/kg/minute or 5 mg/minute.[6] Central or large peripheral vein is preferred.[4]
Monitoring	Oral: Closely monitor BP - Measure BP at 30-minute intervals for 2 hours following the first dose and 30 minutes following the first dose of any increase in dosage. BP is monitored at least twice daily for inpatients once a maintenance dose is achieved. IV: Continuous monitoring of blood pressure and heart rate is required.[6]
Contraindications	Hypersensitivity to hydralazine or components of the formulation.
Precautions	Neutropenia Severe renal impairment Hydralazine Link contains propylene glycol (103.6mg/mL). Co-administration with any substrate of alcohol dehydrogenase e.g. ethanol may induce serious adverse effects in neonates.[6]
Drug interactions	Use with caution when combining with other antihypertensive drugs.
Adverse reactions	Tachycardia Fluid retention Hypotension Agranulocytosis Drug-induced lupus like syndrome[7]
Compatibility	Oral: Not applicable. IV Fluids: Sodium chloride 0.9%[5] Y-site: Heparin[5]
Incompatibility	Oral: Not applicable IV Fluids: Glucose solutions[5] Y site: Aciclovir, ampicillin, azathioprine, cefazolin, cefotaxime, cefoxitin, ceftazidime, ceftriaxone, ertapenem, folic acid, foscarnet, furosemide, ganciclovir, glyceryl trinitrate, haloperidol, lactate, indometacin, lorazepam, methylprednisolone sodium succinate, piperacillin-tazobactam, potassium acetate, sodium acetate, sodium ascorbate, sodium calcium edetate, sodium nitroprusside, tigecycline, urokinase.[5]
Stability	Tablet dispersed in water: Make a fresh solution for each dose and use immediately. Discard unused portion. Compounded suspension/solution: Check with pharmacy department. IV: Reconstitute and dilute immediately before use. Only if necessary reconstituted and diluted solutions are stable for 24 hours stored at 2–8°C.
Storage	Tablets: Store below 25°C. Protect from light. Compounded suspension/solution: Check with pharmacy department. IV ampoule/vial: Store below 25°C. Do not freeze. Protect from light.
Excipients	Oral: colloidal anhydrous silica, disodium edetate, magnesium stearate, microcrystalline cellulose, pregelatinized maize starch, purified talc, sodium starch glycollate and Opadry Pink OY-LS-34902 IV: Hydralazine Link solution - propylene glycol (103.6mg), water for injections, sodium hydroxide and hydrochloric acid for pH adjustment.
Special comments	
Evidence	**Efficacy** Systemic hypertension There are no trials on the efficacy and safety of hydralazine in neonatal hypertension and the dosing recommendations in this formulary are adapted from expert reviews.[1,3,8,9] However, Pediatrix Medical Group survey reported that hydralazine followed by captopril and amlodipine are among the most commonly prescribed anti-hypertensives in preterm infants ≤ 32 weeks and ≤ 1500 g birthweight.[10] Oral antihypertensive agents such as hydralazine are reserved for infants with less severe hypertension or infants whose acute hypertension has been controlled with intravenous infusions and are ready to be transitioned to chronic therapy.[8] Chronic lung disease with pulmonary arterial hypertension and/or hypoxaemic respiratory failure

	Kawaguchi et al, in their Cochrane review found no trials to determine the safety and efficacy of hydralazine in low birth weight infants with persistent hypoxemic respiratory failure. There is insufficient evidence to suggest hydralazine for this indication.[11] **Safety** Intravenous administration can cause unpredictable drop in blood pressure.[1] A lupus-like-syndrome has been reported in a mother and neonate following maternal treatment with hydralazine for preeclampsia.[7] Hydralazine can cause tachycardia, facial flushing and headache due to unabated sympathetic nervous system stimulation. In addition, it can cause salt and water retention and can be combined with a diuretic (usually a loop diuretic). Hydralazine can cause pancytopenia, fever or lupus-like syndrome in patients who are slow acetylators.[12] **Pharmacokinetics** 88-90% protein bound. Oral route: Onset of action is 1 hour with time to peak concentrations in 1-2 hours. Elimination half-life is 3-5 hours. Intravenous route: Onset of action is 5-15 minutes with peak response in 10-80 minutes.[13]
Practice points	
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VERSION/NUMBER	DATE
Original 1.0	25/11/2021
Current 1.0 (minor errata)	5/02/2026
REVIEW	25/11/2026

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Suggested citation
Australasian Neonatal Medicines Formulary (ANMF). Hydralazine. Version number: 1 (minor errata). Date of publication 5/02/2026. https://www.anmfonline.org/