hydrALAZINe
Newborn use only

2026

Key points	Intravenous administration can cause unpredictable drop in blood pressure (BP).[1] Tachycardia and fluid retention are common side effects.[1]
Indication	**Hypertension**
Action	Direct peripheral arterial vasodilator. Dilatation of arterioles decreases systemic vascular resistance.[2]
Contraindications	Hypersensitivity to hydralazine or components of the formulation. Severe tachycardia and heart failure with a high cardiac output.
Precautions	Neutropenia Severe renal impairment
Dose	**Oral** 0.25 to 1 mg/kg/dose 8th or 6th hourly.[1,4,6] Maximum dose is 7.5 mg/kg/day.[1] Always start with a lower dose and increase the dose as needed.[5] **IV intermittent** 0.15 to 0.6 **mg**/kg/dose every 4 or 6 hourly as needed.[1,4,6] **IV continuous** 0.2 **microgram**/kg/minute[5] **Conversion from IV to oral route** Bioavailability of oral hydralazine is lower than IV.[7,8] Care should be taken when converting IV to oral dosing (1:2 ratio) or oral to IV dosing (2:1 ratio).[9]
Dose adjustment	**Therapeutic hypothermia:** No information. **ECMO:** No information. **Renal impairment:** The dose or the dosing interval may need to be adapted according to the clinical response to avoid accumulation of the active substance. Start at lower dose and titrate with response.[2] **Hepatic impairment:** The dose or the dosing interval may need to be adapted according to the clinical response to avoid accumulation of the active substance. Start at lower dose and titrate with response.[2]
Maximum dose	ORAL: 7.5 mg/kg/**DAY**[1] IV: 2 mg/kg/**DAY**[5]
Route	Oral, IV
Presentation	**ORAL** Alphapress tablets: 25mg and 50mg Oral solution/suspension compounded by pharmacy (check which strength is stocked with pharmacy). **IV** Apresoline powder for injection 20mg ampoule (preferred) Hydralazine HCl Injection, USP (Eugia, USA)- 20mg/mL vial. **Note:** The injection can also be given into the enteral feeding tube. Requires reconstitution and may be diluted with water if required.[3]
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] Note: Make a fresh solution for each dose and use immediately. Discard unused portion. **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] Note: Make a fresh solution for each dose and use immediately. Discard unused portion. **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.[3]

	NOTE: Use the smallest volume syringe available/suitable for drawing up the drug for the preparation. (e.g. for <1 mL draw up – use 1 mL syringe). For 10 mL syringe - Recommend using syringe that has markings at 0.2mL increments. **IV*** <u>Apresoline 20mg powder for injection:</u> 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] <u>Hydralazine HCl Injection, USP (Eugia, USA):</u> 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] *Hydralazine may react with metals (e.g. filters, needles) and cause discoloured solutions, often yellow or pink. Avoid prolonged contact with metal components; prepare just prior to use.[4]
Compatibility	Fluids: Sodium chloride 0.9%[11] Amino acids at Y site: Incompatible. Lipid emulsion at Y site: No information. Y-site: amiODAROne, anidulafungin, asparaginase, atenolol, CYCLOPHOSPHamide, etoposide, gatifloxacin, HYDROmorphone, kanamycin, linEXOLID, metronidazole, milrinone lactate, octreotide, pamidronate, pancuronium, streptomycin sulphate, vecuronium.
Incompatibility	Fluids: Glucose solutions[11] Amino acids at Y site: Incompatible. Lipid emulsion at Y site: No information. Y-site: aciclovir, amphotericin B, ascorbic acid, azATHIOPRINE, cefaZOLin, cefOTAXIME, cefoperazone, cefTRIAXONE, cefTAZIDIME, cefOXITIN, cefuroxime, chlorothiazide, DIAzepam, diazoxide, ertapenem, folic acid, foscarnet, ganciclovir, haloperidol, indometacin, LORazepam, meropenem, methyl prednisolone, multivitamin, pantoprazole, phenytoin, piperacillin-tazobactam, potassium acetate, sodium acetate, sodium nitroprusside, sulfamethoxazole-trimETHOPRIM, ticarcillin disodium, urokinase,
Administration	Oral: Give with feeds to enhance absorption. IV: Inject over 5-20 minutes (consensus). 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 cardiac monitoring
Drug Interactions	Use with caution when combining with other antihypertensive drugs.
Adverse Reactions	Tachycardia Fluid retention Hypotension Agranulocytosis Drug-induced lupus like syndrome[10]
Overdose	AUSTRALIA: Contact the Poisons Information Centre on **13 11 26** for management NEW ZEALAND: Contact the National Poisons Centre on **0800 764 766** for management
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. Continuous IV infusion should be used within 24 hours.
Storage	Tablets: Store below 25°C. Protect from light. Compounded solution/suspension: Check with pharmacy department.

	IV ampoule/vial: Store below 25°C. Do not freeze. Protect from light.
Excipients	**ORAL** Alphapress tablets: colloidal anhydrous silica, disodium edetate, magnesium stearate, microcrystalline cellulose, pregelatinised maize starch, purified talc, sodium starch glycollate and Opadry Pink OY-LS-34902 (ARTG PI No: 2948) (50 mg strength only) Oral solution/suspension: check with pharmacy department **IV** Apresoline powder for injection 20mg ampoule (preferred): none Hydralazine HCl Injection, USP (Eugia, USA) - 20mg/mL vial: propylene glycol, sodium hydroxide, hydrochloric acid, water, methylparaben, propylparaben.
Evidence	**Background** Hydralazine is a vasodilator through direct relaxation of vascular smooth muscle of arterioles. There is a reflex sympathetic action to compensate for fall in blood pressure and this sympathetic reflex activity results in tachycardia and increased stroke volume and cardiac output. Up to 75% of the therapeutic effect of hydralazine can be lost by this reflex action.[2] **Efficacy** The use of antihypertensives in neonatal population is commonly guided by expert opinion.[1,4-6] However, studies reported that hydralazine is among the most commonly prescribed anti-hypertensives in preterm infants.[12-15] Oral hydralazine is generally 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.[4] **Safety** Hydralazine is generally well tolerated. However, intravenous administration can cause unpredictable and excessive drop in blood pressure.[1,4,16] Hydralazine can cause reflex sympathetic stimulation and increases heart rate and cardiac output. In addition, it can cause salt and water retention.[1,2] A lupus-like-syndrome has been reported in a mother and neonate following maternal treatment with hydralazine for preeclampsia.[10] **Pharmacokinetics** Oral hydralazine has a low to moderate bioavailability of approximately 10%–50% due to significant, rapid, and genetically determined first-pass metabolism, particularly in fast acetylators. While absorption from the gastrointestinal tract is almost complete, the drug is heavily metabolized, primarily in the liver and gut wall.[7,8] Hydralazine and its metabolites are rapidly excreted by the kidney.[2] In severe renal impairment, lower doses may be sufficient to obtain therapeutic effect due to reduced excretion.[2]
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