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Medicine Guideline

Amiodarone Intravenous

Areas where Protocol/Guideline applicable	Critical Care Services (i.e., Intensive Care, Emergency Medicine, Coronary Care) where close monitoring of arterial and venous pressure, and continuous ECG can be performed.
Authorised Prescribers:	Critical Care or Cardiology Staff Specialist, or Medical Officers under their direct supervision

Indication for use	• Advanced Life Support algorithm for treatment of VT/VF
	• Treatment and prophylaxis of serious tachyarrhythmia's refractory to other treatment, including;
	  ○ Supraventricular and ventricular tachycardia
	  ○ Ventricular fibrillation
	  ○ Atrial fibrillation
	  ○ Atrial flutter
	  ○ Wolff-Parkinson-White syndrome (orthodromic conduction)

Contra-indications	• Hypersensitivity to Amiodarone or iodine • Pregnancy and lactation • Severe hypotension (*relative contraindication*) • Sinus bradycardia or sinoatrial heart block, second or third degree AV block (unless artificial pacemaker present) • Cardiogenic shock (unless artificial pacemaker present) (*relative contraindication*)
Precautions	• It is recommended to perform an electrocardiogram (ECG) and serum potassium measurement prior to initiation of treatment and daily whilst treatment continues • Pulmonary disease (particularly with reduced diffusion capacity – e.g. pulmonary fibrosis or interstitial lung disease), less reserve to cope with pulmonary adverse effects • Very rare cases of interstitial pneumonitis and pulmonary fibrosis have been reported with intravenous Amiodarone. Chest X-Ray (CXR) should be performed in patients who develop unexplained dyspnoea • Electrolyte disturbances (e.g., hyperkalaemia, hypomagnesaemia - correct before starting treatment if possible) • Heart failure: caution should be exercised as existing heart failure may be worsened • Hepatic dysfunction (use with extreme caution) • Evidence or family history of thyroid dysfunction

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Important Drug Interactions	• Amiodarone may enhance the anticoagulant effect of **warfarin**. Caution should be used when initiating amiodarone in patients on warfarin, monitor INR closely[11]
	• Co-administration of Amiodarone with **drugs known to prolong the QT interval** may increase risk of torsades de pointes and must be based on a careful assessment of the potential risks and benefits for each patient.
	  ○ class 1A antiarrhythmics (e.g., quinidine, procainamide)
	  ○ class III antiarrhythmics (e.g., sotalol, cisapride)
	  ○ some anti-infectives (e.g., erythromycin, roxithromycin, fluconazole, voriconazole, moxifloxacin)
	  ○ tricyclic antidepressants (e.g., amitriptylline, clomipramine)
	  ○ some antipsychotics (e.g., amisulpride, haloperidol, droperidol)
	  ○ drugs that increase arrhythmogenic potential indirectly, i.e., by causing hypokalaemia (e.g., thiazide diuretics)
	• Symptomatic bradycardia from marked depression of sinus or A-V node function may occur in patients on **beta blockers** or heart rate lowering calcium antagonists (**verapamil and diltiazem**)
	• May raise plasma **digoxin** level	

Dosage	**Maximum recommended dose 1200 mg in 24 hours*.** In some circumstances patients may require higher doses of amiodarone. These cases must be discussed with a consultant and the dose confirmed by them.	
	For cardiac arrest management Code Blue team will follow ALS algorithm:	Initial bolus dose is 300 mg. An additional dose of 150 mg could be considered. This may be followed by an infusion over 24 hours.
	Non-cardiac arrest	Loading dose: 300 mg over 30 – 60 minutes Maintenance dose: 900 mg over 24 hours
Duration of therapy	Depends on clinical response. Transition to oral amiodarone therapy if / when appropriate.	
Prescribing Instructions	Prescribed on the eMR or eRIC. In the absence of eMM systems, the appropriate paper medication chart may be used. Therapeutic endpoints MUST be documented.	
Preparation Instructions	• Must be diluted with 5% glucose – *amiodarone is **NOT** compatible with Sodium Chloride 0.9%* • Prepare infusion immediately prior to use • Do not use ampoules if there is any visible crystallisation, cloudiness, or particulate matter. The solution must be completely clear before administration. • Protect from light. Ampoules should remain in their original packaging to protect from light exposure until immediately prior to use.	

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Administration Instructions

- Administration of amiodarone through a peripheral vein is associated with a very high incidence of thrombophlebitis.
- A central line should be used when high concentrations (i.e., greater than 2 mg/mL) are administered, or rapid infusion rates anticipated. A central line should also be considered where continuous infusion of amiodarone is required.
- **If the patient has no central venous access, to avoid delay of treatment, loading dose only may be given via a large peripheral cannula in a large vein. Concentration must NOT be greater than 2 mg/mL for infusion via peripheral line**
- Amiodarone requires a dedicated infusion line and must not be administered with other drugs; however it can be administered via a Y-site with other compatible medications (refer to Australian Injectable Drugs Handbook for compatibilities)
- **Continuous infusions that will exceed 2 hours must be prepared in rigid PVC or non- PVC burettes and PVC free tubing with 0.22 micron in line filter (blue line) to be used**

  Note: Fresenius Kabi free flex® bags are non-PVC bags

For cardiac arrest management Code Blue team will follow ALS algorithm:

Bolus doses: Dilute 150 - 300 mg in 10 – 20 mL of Glucose 5% and inject over 1 to 2 minutes. If necessary, the dose can be injected undiluted and followed immediately with at least 20 mL of glucose 5% or sodium chloride 0.9%.
If continuous infusion required, refer to non-cardiac arrest maintenance dose.

Non-cardiac arrest

Solutions of 600 microg/mL to 6 mg/mL of amiodarone in Glucose 5% are stable for 24 hours at 25 °C.

Do not use concentrations **less than 600 microg/mL**.

Solutions of **greater than 6 mg/mL** are stable for 12 hours ONLY. Administer via 2 infusions / syringes and changed after 12 hours.

Dose	Access	Preparation	Max. Concentration	Administration
LOADING (use non-PVC infusion container)				
300 mg	Peripheral Line	Remove 100 mL from a 250 mL bag of 5% Glucose and add 300 mg Amiodarone	2 mg/mL	Infuse over 1 hour
	Central Line	300 mg in 50 mL 5% Glucose	6 mg/mL	Infuse over 30 minutes
CONTINUOUS INFUSION (via infusion pump with 0.22 micron filter)				
900 mg*	Peripheral Line	450 mg in 250 mL 5% Glucose	2 mg/mL	Infuse at 21 mL/hour
	Central Line	450 mg in 50 mL 5% Glucose	9 mg/mL	Infuse at 4.2 mL/hour
		450 mg dilute to 24 mL 5% Glucose	18.75 mg/mL	Infuse at 2 mL/hour

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NOTE: As per NSW Safety Notice 001/22 *Avoiding thrombophlebitis associated with intravenous Amiodarone (updated)* the following is recommended:

- For administration of a **single dose** via a peripheral intravenous cannula:
  - Dilute in glucose 5% to a maximum concentration of 2 mg/mL and infuse via an infusion device over a period of 20 minutes to 2 hours. Amiodarone should only ever be administered over shorter time periods in emergency situations
  - Avoid areas of flexion and ensure peripheral intravenous cannula is stabilised
  - Use the most appropriate cannula size for the vein. Use of a peripheral intravenous cannula that is too large in diameter for the vein increases the risk of phlebitis

For administration of **a high concentration infusion (greater than 2 mg/mL) or when repeated or continuous intravenous administration is anticipated** consider administration via a central venous access device (CVAD)

The use of in-line filters may reduce risk of thrombophlebitis and is recommended

Monitoring requirements Safety Effectiveness (state objective criteria)	• Continuous ECG monitoring in a critical care area. • Baseline 12 lead ECG. • Baseline troponin, electrolytes, LFTs and thyroid function. • Ensure defibrillation equipment is readily available. • Concomitant therapy with digoxin may elevate serum digoxin levels • Monitor hepatic enzymes, serum potassium, and antiarrhythmics. • If on warfarin monitor INR level.
Adverse Effects	○ Bradycardia, hypotension ○ Thrombophlebitis (therefore use central venous catheter/PICC line, see administration guidelines below) ○ Nausea and vomiting (especially while loading), constipation, loss of appetitie ○ Transient elevations of liver enzymes ○ Thyroid dysfunction – Both hyperthyroidism and hypothyroidism have been reported with the use of amiodarone. ○ Photosensitivity, bluish skin discolouration, slate grey facial pigmentation ○ Headache, dizziness, vertigo, fatigue, sleep disorders, vivid dreams, paraesthesia, gait abnormalities ○ Pulmonary toxicity ○ Corneal deposits, these develop commonly, but are rarely associated with visual disturbance. If blurred or decreased vision occurs, ophthalmological examination (including fundoscopy) should be promptly performed. Appearance of optic neuropathy and/or optic neuritis requires amiodarone withdrawal due to the potential progression to blindness
Documentation	• Checked and prepared by two Medical or Nursing staff following the five rights as per NSW Health PD2013_043 *Medication Handling in NSW Public Health Facilities* • Syringe and line must be labelled as per NSW Health PD2016_058 *User-applied Labelling of Injectable Medicines, Fluids and Lines* • Adverse drug reaction (ADR) history and new ADRs during an episode of care must be documented as specified in SESLHDPR/267 *Medicine: Continuity of Management and Documentation*

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Management of Complications	Hypotension is common in patients receiving intravenous amiodarone and may benefit from a decrease in the infusion rate. Monitor closely.
Basis of Protocol/Guideline: (including sources of evidence, references)	1. Hughes, M., Binning, A. (2000) 'Intravenous Amiodarone in Intensive Care'. Intensive Care Medicine (2000) 26: 1730 -1739 2. Opie, L.H., Gersh, B. J. (2008) Drugs for the Heart 3. MIMS Online. Amiodarone GH Injection. 30 May 2018. 4. Therapeutic Guidelines. Cardiovascular. 2023. 5. Australian Injectable Drugs Handbook. 9th ed. Collingwood: Society of Hospital Pharmacists of Australia; 2024 6. Australian Resuscitation Council ALS Guidelines, August 2023 7. Australian Medicines Handbook. Amiodarone. July 2024. 8. NSW Health Safety Notice 007/22. Avoiding thrombophlebitis with intravenous amiodarone - UPDATED. 18 July 2022. 9. NSW Health. PD2019_040. Intravascular Access Devices (IVAD) - Infection Prevention & Control. 16 August 2019. 10. United Kingdom Clinical Pharmacy Association (December 2012), Minimum Infusion Volumes for fluid restricted critically ill patients, version 4.4. 11. Oragano CA, et al Phlebitis in intravenous amiodarone administration: incidence and contributing Factors. Critical Care Nurse. 2019 Feb; 39(1): e1-e12 12. Gorski LA, et al. Infusion therapy standards of practice. Journal of Infusion Nursing. 2021 Jan-Feb; 44(suppl 1): S1-S224 13. Norton L, et al Phlebitis in amiodarone administration: incidence, contributing factors, and clinical implications. American Journal of Critical Care. 2013; 22: 498-50 14. Up-To-Date. Amiodarone: Clinical uses. E.G., Giardina & R., Passman. July 24, 2023.
Groups consulted in development of this guideline	Developed in reference to; • POWH CLIN059 Critical Care Services Intravenous Drug Protocols – Amiodarone • SGH-TSH CLIN671 Clinical (Drug Information) Business Rule - Amiodarone

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