

Amiodarone (oral)

Cardiology Shared Care Guideline

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Specialist Details	Patient Identifier
Name: _____	Date: _____
Location: _____	
Tel: _____	

Introduction

Licensed indication:

Amiodarone is indicated only for the treatment of severe rhythm disorders not responding to other therapies or when other treatment cannot be used.

Atrial flutter and fibrillation when other drugs cannot be used.

All types of tachyarrhythmias of paroxysmal nature including: supraventricular, nodal and ventricular tachycardias; ventricular fibrillation; when other drugs cannot be used.

Tachyarrhythmias associated with Wolff-Parkinson-White syndrome.

Adult dosage and administration (oral therapy):

Initial stabilisation: Treatment should be started with 200mg three times a day (including post IV loading dose) and may be continued for 1 week.

The dosage should then be reduced to 200mg twice daily for a further week.

Maintenance: After the initial period the dosage should be reduced to 200mg daily, or less if appropriate.

Some groups of patients e.g. elderly may require both a lower initial stabilisation dose and lower maintenance dose.

Rarely, the patient may require a higher maintenance dose. The scored 100mg tablet should be used to titrate the minimum dosage required to maintain control of the arrhythmia. The maintenance dose should be regularly reviewed, especially where this exceeds 200mg daily.

Available as: Amiodarone 100mg; 200mg tablets.

Hospital Specialist Responsibilities

- Arrange shared care with the patient's GP.
- Provide patient/carer with relevant (preferably written) information on use, side-effects and need for monitoring of medication.
- Provide shared care monitoring record booklet.
- Baseline tests:
 - TFT
 - U & E
 - LFT
 - ECG
 - Lung function tests (spirometry, lung volumes and diffusing capacity/transfer factor)
 - Chest X-ray
- Review treatment with digoxin if applicable and if treatment is to continue, half the dose of digoxin and monitor digoxin levels.
- INR levels should be closely monitored if applicable.
- Review results of safety monitoring and request additional tests as required.
- Monitor disease response to treatment and annually the need to continue therapy.
- Continue to review the patient at agreed specified intervals, sending a written summary to the GP whenever the patient is reviewed.
- ECG at least annually and review patients for pulmonary toxicity e.g. CXR or lung function tests (as above) annually.
- Provide any other advice or information for the GP including dose adjustments .

GP Responsibilities

- Prescribe amiodarone according to dose advised by specialist.
- A sunblock should be prescribed to protect against photosensitivity.
- Arrange and record on-going monitoring as agreed with specialist:
- **TFT:** every 6 months (including up to 12 months after discontinuation of amiodarone). Clinical Hyperthyroidism: refer urgently and simultaneously to endocrine specialist and the initiating consultant. High FT4, normal TSH: continue amiodarone and discuss with endocrinologist. Hypothyroidism: liaise with initiating specialist.
- **LFT:** every 6 months. If ALT or AST levels are > 3 x upper limit of normal (ULN), continue amiodarone and contact the initiating specialist for advice.
- **U&E:** serum potassium: correct hypokalaemia, refer to initiating specialist for advice.
- Report adverse drug reactions to initiating specialist and usual bodies (e.g. MHRA).
- Ensure no drug interactions with other medicines.

Adverse Effects, Precautions and Contraindications

Very common side effects are: nausea, vomiting, reversible corneal micro-deposits, photosensitivity.

Common side effects are: extrapyramidal tremor, nightmares, sleep disorder, changes in thyroid tests and liver function tests, and jaundice. Bradycardia, (generally moderate and dose related). Slate grey or bluish pigmentations of light-exposed skin, particularly the face, in prolonged treatment with high daily doses.

Pulmonary toxicity: suspect if increasing breathlessness, unexplained cough or new end-inspiratory crepitations develop. Refer urgently to cardiologist. If pulmonary toxicity is suspected a CXR and lung function tests are required.

Very rare side effects include: optic neuropathy/ neuritis, cerebellar ataxia, benign intracranial hypertension, chronic liver disease (sometimes fatal).

Eye examinations should be reserved for patients reporting visual symptoms. If vision is impaired or if optic neuritis or optic neuropathy occur, amiodarone must be stopped and expert advice sought.

Contraindications include:

Sinus bradycardia and sino-atrial heart block: In patients with severe conduction disturbances (high grade AV block, bifascicular or trifascicular block) or sinus node disease, amiodarone should be used only in conjunction with a pacemaker.

Evidence of history of thyroid dysfunction: Thyroid function tests should be performed prior to therapy in all patients.

Known hypersensitivity to iodine or to amiodarone (one 100mg tablet contains approximately 37.5mg iodine), or to any of the excipients.

Pregnancy: amiodarone should be avoided during pregnancy.

Breast feeding: amiodarone is excreted into the breast milk in significant quantities and breast-feeding is contraindicated.

Common Drug Interactions

The combination of amiodarone with drugs which may induce Torsades de Pointes is **contra- indicated:** e.g. quinidine, procainamide, disopyramide, sotalol, intravenous erythromycin, co-trimoxazole, moxifloxacin, chlorpromazine, haloperidol, amisulpiride, lithium, tricyclic anti-depressants, terfenadine, quinine, chloroquine, mefloquine.

Co-administration of amiodarone with other drugs known to prolong the QT interval must be based on a careful assessment of the potential risks and benefits for each patient.

Combined therapy with the following medicines is not recommended: diltiazem, verapamil, stimulant laxatives e.g. senna/bisacodyl.

The concomitant use of **beta-blockers** may be used under specialist supervision. Use with caution in association with: diuretics, systemic corticosteroids, tetracosactrin (may cause hypokalaemia and/or hypomagnesaemia).

Ciclosporin/ tacrolimus/ sirolimus: amiodarone possibly increases plasma concentration of these drugs

Warfarin:

- For patients already taking warfarin, if starting amiodarone the INR may increase thus recheck INR weekly for the next 3 weeks and adjust warfarin dose as required until the INR is stable.
- For patients already taking amiodarone, if starting warfarin, consider using a lower initial dose of warfarin.
- For patients already taking warfarin and amiodarone, if stopping amiodarone the INR may decrease thus recheck INR weekly for the next 3 weeks and adjust warfarin dose as required until the INR is stable.

Digoxin: Amiodarone is not usually used concurrently with digoxin in the non-acute setting and the on-going combination should only be advised by a cardiologist. If concurrent use is required, reduce the previous the dose of digoxin by half and check the digoxin level during amiodarone initiation, or if concerns of digoxin toxicity. After discontinuation of amiodarone, reassess heart rate since digoxin levels will fall and additional rate control may or may not be required.

Statins: Concurrent use with CYP3A4 metabolised statin therapy may increase the risk of muscular toxicity. If statin therapy is required, use of reduced dose atorvastatin or a statin not metabolised by CYP3A4 is preferred. Concurrent use with simvastatin is best avoided, but if co-prescribed, the maximum simvastatin dose should not exceed 20mg daily.

Simprevir and sofosbuvir or sofosbuvir and daclatasvir or sofosbuvir and ledipasvir: Avoid concomitant use of amiodarone unless other antiarrhythmics cannot be given. The combination should only be used under specialist supervision. Closely monitor patients, particularly during the first weeks of treatment. In patients who have stopped amiodarone within the last few months and need to start taking these antiretrovirals monitoring is required due to the long half-life of amiodarone.

Phenytoin: Amiodarone may increase phenytoin levels. The dosage of phenytoin should be reduced if signs of overdose appear and plasma levels may be measured.

Eplerenone: amiodarone is predicted to increase the exposure to eplerenone and the dose of eplerenone should be adjusted.

Flecainide: Amiodarone may increase flecainide plasma levels and the combination should only be considered if under the specific direction of a consultant electro-physiologist (reduce flecainide dose by 50% and monitor plasma levels).

Grapefruit juice should be avoided during treatment with amiodarone.

For any queries relating to this patient's treatment with amiodarone, please contact the specialist named at the top of this document.

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF