**Request to Share Care and Agreement Form**

**Amiodarone tablets for adults used for tachyarrhythmias associated with Wolff-Parkinson-White Syndrome, Atrial Flutter Fibrillation / Atrial Fibrillation, Paroxysmal Tachyarrhythmias and Ventricular Fibrillation when other drugs cannot be used as well as for prior and post Cardioversion or in specific patients who have Heart Failure or Left Ventricular Impairment.   
Shared Care Protocol: Guideline No 17; Version 1.1**

**This Request to Share Care provides Key Primary Care Information on responsibilities and monitoring. The aim is to support the GP to agree to share care arrangements. Refer to Full Shared Care Protocol for further information (page 6 onwards).**

**GP to review and must respond to provider Trust request to share care within 2 weeks using form provided on page 5.**

**For Completion by Specialist (with page 6 Shared Care Agreement Form)**

Addressograph label

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| **Patient name** |  |  |
| **DOB** |  | **OR** |
| **NHS number** |  |  |

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| **Drug(s) Dose and Route at handover:** |  |
| **Indication:** |  |
| **Date of first prescription by specialist:** |  |
| **Patient weight (kg):** |  |
| **Estimated date for prescribing to be continued by the GP:** |  |
| **Next monitoring tests due and dates if not at 12 weekly monitoring:** |  |
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| **Specialist additional comments/advice:** |  |
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| **Key Primary Care Information (refer to Full Shared Care Protocol for further information)**  **GP RESPONSIBILITIES**   |  |  | | --- | --- | | **GP/ Primary care prescriber responsibilities** | | | **1.** | Review the shared care request from the specialist to take on prescribing of amiodarone tablets. Promptly communicate to the specialist if prescribing responsibility is not accepted (within 2 weeks), including the clinical reason. Responsibility cannot be declined on grounds of cost of medication. | | **2.** | Check sufficient information has been provided to take on the responsibility for continued prescribing. Request any missing information to be provided from the specialist before taking on the prescribing in primary care. (Refer to point 7 of the ‘Specialist Responsibilities’ on page 8). | | **3.** | If accepted, prescribe ongoing treatment as detailed in the specialist’s request and as per (Adult dosage and administration section on page 6) taking into any account potential drug interactions (page 11) | | **4.** | Link amiodarone to the indication on the GP prescribing system. | | **5.** | Conduct the required ongoing monitoring as discussed with the specialist and outlined below. Contact the specialist if any abnormal results as appropriate (see monitoring and actions to be taken if abnormal result section below). | | **6.** | Monitor patients during routine medication reviews for efficacy, adverse effects, adherence, and drug interactions. Contact the specialist for advice where necessary. Manage adverse effects as detailed in the (side effects and actions to be taken section on page 10) and discuss with specialist team when required.  Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). | | **7.** | Stop amiodarone and make an urgent referral to the specialist if hyperthyroidism, thyrotoxicosis, new or worsening arrhythmia or heart block, ophthalmological effects, hepatotoxicity, pulmonary toxicity or bullous skin reactions are suspected. | | **8** | Reinforce patient advice/responsibilities including when to seek medical attention. | | **9.** | Provide advice on the need for contraception to male and female patients at each review. Refer the management back to the specialist if the patient becomes or plans to become pregnant. | | **10.** | Stop treatment as appropriate and advised by the specialist |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **MONITORING AND ACTIONS TO BE TAKEN**  **Monitoring**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Monitoring table** | | **Hospital specialist** | **Hospital specialist** | **GP** | | **Test** | **Indication** | Pre-treatment baseline | Ongoing | Ongoing | | Liver function tests (LFTs) particularly transaminases) | Baseline and ongoing assessment including dose adjustment to confirm safe prescribing | √ | If needed | Every 6 months during treatment, and 6 months after discontinuation.  Thyroid function should continue to be monitored for up to 12 months after discontinuation, with frequency determined clinically. | | Urea and electrolytes (U&E’s) | | Thyroid function tests (free T4, free T3 and TSH) | | Electrocardiogram (ECG) | Baseline and ongoing assessment to confirm safe to prescribing | √ | At least annually | Ensure ECG has been done by specialists | | Chest X-ray | Baseline assessment to confirm safe prescribing | If needed | Usually done within a year of initiation or  If clinically required | Not routinely required | | Patients taking warfarin/digoxin:  Warfarin - monitor international normalised ratio (INR) at baseline and during dose stabilisation period.  Digoxin: concomitant use would usually involve a digoxin dose reduction. The dose would be determined on individual basis by specialist. Digoxin levels should be monitored appropriately. | Baseline assessment and dose stabilisation | If clinically indicated | If needed | Not routinely required |   **Action to be taken if abnormal result**  Normal reference range may vary slightly between labs. Results should be recorded in the patient’s shared care monitoring record booklet (where in use). Please note an unusual fall or rise or a consistent downward or upward trend in any value should prompt review of the patient and extra vigilance. Some patients may have abnormal baseline values, specialist will advise.   |  |  | | --- | --- | | **Abnormal result** | **Action for GP/ Primary Care** | | Electrolyte deficiency | Continue amiodarone. Correct deficiency as per local guidelines. Review other medicines that may be contributing to a deficiency. | | **Cardiovascular effects:** |  | | Bradycardia: Heart rate 50 - 60bpm without symptoms | Continue amiodarone. Repeat monitoring. No action required unless symptoms develop or heart rate decreases further. | | Heart rate ≤ 50bpm, or ≤ 60bpm with symptoms | Discuss with specialist team; dose reduction may be required | | Worsening of arrhythmia, new arrhythmia, or heart block | **Stop amiodarone.** Urgent referral to initiating specialist. | | **Thyroid dysfunction**: |  | | Borderline results according to local reference range | Continue amiodarone. Repeat test after 6 weeks. | | Hyperthyroidism / thyrotoxicity:  high T4, normal/high T3, low TSH | **Stop amiodarone.** Urgent referral to initiating specialist and endocrinologist. | | Hypothyroidism:  low/normal T4, low/normal T3, high TSH | Continue amiodarone. Inform initiating specialist. Consider starting levothyroxine based on initiating specialist’s advice. Monitor levothyroxine according to local pathways. | | Subclinical hypothyroidism  normal T4, raised TSH; clinical features not overtly manifest | Contact specialist team for advice, which may include input from endocrinology services.  Anticipate the need for additional monitoring, investigations and potentially thyroid hormone replacement based on specialist recommendations. | | **Hepatotoxicity**:  Abnormal LFTs +/- symptoms of hepatic injury (e.g. hepatomegaly, weakness, ascites, jaundice) | If serum transaminases elevated >3xULN but no symptoms of hepatic injury continue amiodarone and – repeat LFTs in 2 weeks. If still elevated may require dose reduction; discuss with specialist.  If serum transaminases >5xULN or any symptoms of hepatic injury- **stop amiodarone**. Urgent referral to initiating specialist and hepatologist. | | |

* The expectation is that this information along with the full protocol provides sufficient information to enable GPs to be confident to take on the clinical & legal responsibility for prescribing and monitoring.
* Prescribing and monitoring responsibility will only be transferred under this shared care protocol when:
* Specialist has initiated treatment and prescribed/monitored treatment for initial stabilisation period.
* Specialist has provided pre-treatment counselling and discussed patient responsibilities, preferences and obtained consent to shared care arrangements.
* Specialist and patient have completed and signed the shared care agreement form (page 6).

**Shared Care Agreement Form**

**This form is used to agree shared care between the specialist, patient and GP.**

**Specialist and patient agreement**

**By signing below we accept:**

* the [Hertfordshire and West Essex Area Prescribing Committee (HWE APC) shared care principles](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c)
* the requirements and responsibilities defined in this drug specific shared care protocol

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| **Specialist name:** | **Patient name or addressograph label:** |
| **Designation:** |
| **Provider Trust:** |
| **Direct telephone number:** |
| **Email:**  **Email (for use by GP to respond to request to share care):** |
| **Date:** | **Specialist Signature:** |
| **Date:** | **Patient Signature or specialist confirmation of patient agreement to shared care arrangement:** |

**GP response to shared care**

**Please return to specialist within two weeks of receipt of request to share care.**

***This form is to be completed by the GP who is requested to share care.***

I agree to accept shared care for this patient as set out in this shared care protocol and [Hertfordshire and West Essex (HWE) ICB Principles for Shared Care](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c)

I do not accept shared care for this patient

My reason(s) for not prescribing are given below:

Please note that GP agreement is voluntary, with the right to decline to share care if for any reason you do not feel confident in accepting clinical responsibility. Refusal should not be for financial reasons.

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| **GP name:** | **Practice address /stamp:** |
| **Direct telephone number:** |
| **Email:** |
| **Date:** | **GP Signature:** |

**Please return a copy of the completed form to the requesting specialist within two weeks of receipt of request to share care (preferably by email).**

1. Specialist to retain copy in patient’s hospital records.
2. Copy to be given to patient.
3. GP to retain copy in patient’s notes.

**Full Shared Care Protocol**

**Amiodarone tablets for adults used for tachyarrhythmias associated with Wolff-Parkinson-White Syndrome, Atrial Flutter Fibrillation / Atrial Fibrillation, Paroxysmal Tachyarrhythmias and Ventricular Fibrillation when other drugs cannot be used as well as for prior and post Cardioversion or in specific patients who have Heart Failure or Left Ventricular Impairment.**

**Shared Care Protocol: Guideline No 17; Version 1.1**

**This full protocol provides prescribing and monitoring guidance. It should be read in conjunction with** [**Hertfordshire and West Essex (HWE) ICB Principles for Shared Care**](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c)**,** [**Summary of Product Characteristics (SPC)**](https://www.medicines.org.uk/emc/product/13964/smpc) **and the** [**BNF**](https://bnf.nice.org.uk/drugs/amiodarone-hydrochloride/)**.**

**BACKGROUND AND INDICATION(S) FOR USE**

The HWE ICS formulary status of oral amiodarone tablets is AMBER PROTOCOL (continuation of prescribing in primary care using this shared care protocol).

Amiodarone is used for the for the following licensed indications, which include:

• Tachyarrhythmias associated with Wolff-Parkinson-White Syndrome.

• Atrial flutter fibrillation / atrial fibrillation when other drugs cannot be used.

• All types of tachyarrhythmias of paroxysmal nature including supraventricular, nodal and

ventricular tachycardias and ventricular fibrillation when other drugs cannot be used.

NHSE also recommends amiodarone prescribing for prior and post cardioversion or in specific patients who also have heart failure or left ventricular impairment.

Amiodarone is not recommended to be prescribed for off-label indications.

Amiodarone is also used in the treatment of severe cardiac rhythm disorders where other treatments either cannot be used or have failed. It may also be suitable in patients prior and post cardioversion or in specific patients who have heart failure or left ventricular impairment.

Amiodarone has potentially serious adverse effects and its use requires regular monitoring. Due to the significant safety concerns, NHS England (NHSE) and NHS Clinical Commissioners’ (NHSCC) [guidance](https://www.england.nhs.uk/medicines-2/items-which-should-not-be-routinely-prescribed/) advises that prescribers should not initiate amiodarone in primary care for any new patients. In exceptional circumstances, if there is a clinical need for amiodarone to be prescribed, this must be initiated by a specialist and only continued in primary care using this prescribing support document which is in line with

NICE clinical guidance Atrial fibrillation: [NG196](https://www.nice.org.uk/guidance/ng196/resources/atrial-fibrillation-diagnosis-and-management-pdf-66142085507269) and [NHSE Amiodarone for adults SCP](https://www.england.nhs.uk/publication/shared-care-protocols/#heading-1). NICE has made a “Do not offer amiodarone for long-term rate control” recommendation.

Where there is an existing cohort of patients taking amiodarone that is not in line with this prescribing support document, patients should be reviewed to ensure that prescribing remains safe and appropriate.

This document applies to adults aged 18 and over. Refer to [BNF](https://bnf.nice.org.uk/drugs/) & [SPC](https://www.medicines.org.uk/emc/) for full prescribing information.

**DOSAGE, ROUTE OF ADMINISTRATION AND DURATION OF TREATMENT**

**Adult dosage and administration**

• Request to shared care of amiodarone prescribing and monitoring from secondary to primary care is normally after at least 12 weeks, and when the patient’s dose has been optimised and with satisfactory investigation results for at least 4 weeks by the specialist.

•The duration of treatment & frequency of review will be determined by the specialist and communicated to the GP, based on clinical response and tolerability.

• All dose or formulation adjustments should be on the advice/guidance of initiating specialist unless directions have been discussed and agreed with the primary care clinician.

•Termination of treatment should be in line with this document and/or on the advice/guidance of initiating specialist.

Initial stabilisation:

• 200mg three times per day for one week, then reduce to 200mg twice per day for one week.

• Amiodarone is initiated with a loading dose to achieve adequate tissue levels rapidly. Rarely, the specialist team may use an alternative loading regimen.

• The loading period must be prescribed by the initiating specialist.

Maintenance dose (following initial stabilisation):

• 200mg per day, or less if appropriate. The minimum dose required to control the arrhythmia should be used.

• Rarely, a higher maintenance dose may be required. The maintenance dose should be reviewed regularly, particularly if it exceeds 200mg per day.

• The initial maintenance dose must be prescribed by the initiating specialist.

Conditions requiring dose adjustment:

Although there is no evidence that dose requirements for elderly patients are lower, they may be more susceptible to bradycardia and conduction defects if too high a dose is prescribed. The minimum effective dose should be used. Particular attention should be paid to monitoring thyroid function. Dose adjustment must be specified by the specialist.

Swallowing difficulties

Please refer to the [‘specials’ alternative guidance](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.hweclinicalguidance.nhs.uk%2Fall-clinical-areas-documents%2Fdownload%3Fcid%3D2274%26checksum%3D95f8d9901ca8878e291552f001f67692&data=05%7C02%7Cheernamehta%40nhs.net%7Ccba67ac584344a90298108dcafcc3bcd%7C37c354b285b047f5b22207b48d774ee3%7C0%7C0%7C638578538908037976%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=drWPIVzT4RkMn0VJJa96%2F2dIm19xPNtqcc0yghL%2FsEA%3D&reserved=0) for a list of commonly prescribed medicines and alternative methods of administration for patients with swallowing difficulties, feeding tubes or for patients prescribed unlicensed ‘specials’ medication. Each entry takes into account alternative medicines, formulations, cost and licensing. This list is not exhaustive. As not all medicines are listed, please contact the initiating specialist if required for individual patient advice if a patient has a swallowing difficulty.

Pharmaceutical Aspects



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| **SPECIALIST RESPONSIBILITIES INCLUDING PRE-TREATMENT ASSESSMENT**   |  |  | | --- | --- | | **Specialist Responsibilities** | | | **1.** | Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this prescribing support document and amiodarone is initiated for its licenced indications (see section 1 and 2). | | **2.** | Assess for appropriateness of treatment, contraindications, and cautions as well as interactions (see page 11). | | **3.** | Conduct required baseline investigations and initial monitoring (see page 2). | | **4.** | Discuss treatment with patient/carer including the following:   * benefits/risks with shared decision making and consent to treatment * counselling points (See below and [Patient Alert Card](https://www.medicines.org.uk/emc/rmm/2415/Document)) * dose titration schedule * monitoring requirements * potential side effects and actions * provide any relevant information and advice, including patient information leaflets.   The patient should be advised to report any of the following signs or symptoms to their primary care prescriber without delay:   * Breathlessness, non-productive cough or deterioration in general health (e.g. fatigue, unplanned weight loss or gain, fever, heat and cold intolerance). * New or worsening visual disturbances. * Progressive skin rash +/- blisters or mucosal lesions. * Signs and symptoms of bradycardia or heart block, e.g. dizziness, fatigue, fainting, shortness of breath, chest pain or palpitations, confusion or trouble concentrating.   Further patient advice should include:   * To use appropriate self-care against the possibility of phototoxic reactions: e.g. sun avoidance, protective clothing, avoiding tanning (including tanning beds) and to purchase and use a broad spectrum sunscreen (at least SPF30). These measures to be continued for the duration of therapy and for several months after discontinuation. * If taking a statin and amiodarone, to report any signs of unexplained muscle pain, tenderness, weakness or dark coloured urine. * Avoid grapefruit and grapefruit juice while taking amiodarone and for several months after discontinuation. * Although there have been no case reports on enhanced hepatoxicity with alcohol, patients should be advised to moderate their alcohol intake to no more than 14 units per week while taking amiodarone. | | **5.** | Initiate and optimise treatment. Prescribe the maintenance treatment for at least 4 weeks and until optimised on the maintenance once daily dose and assessed for clinical effectiveness and tolerability prior to transfer to primary care (see section 4). | | **6.** | Undertake routine specialist reviews and follow up appointments, which includes dose titration and monitoring, assessment of the response to treatment and tolerability (see section 5). | | **7.** | Once treatment is optimised, send this shared care protocol to patient’s GP practice requesting shared care, detailing the following:   * Diagnosis * Ongoing maintenance dose * Relevant test results * Monitoring requirements and when next due * Stopping and referral criteria * Specialist team contact details for GPs to obtain advice and support | | **8.** | Ensure that patient/carer is informed and made aware of their responsibilities (see patient/carer responsibilities). | | **9.** | Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care. | | **10.** | Provide advice on the need for contraception to male and female patients on initiation and at each review. Reassume prescribing responsibilities if a patient becomes or wishes to become pregnant. | | **11.** | Provide advice to primary care on the management of adverse effects if required. | | **12.** | If ongoing review by specialist, following review advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring remains appropriate. | |

**GP RESPONSIBILITIES**

Refer to pages 1 - 2 and GP Considerations for Shared Care page 13.

**PATIENT RESPONSIBILITIES IN COOPERATION WITH SPECIALIST AND GP**

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| **Patient/Carer responsibilities** | |
| **1.** | Report to their specialist or GP if they do not have a clear understanding of or have any concerns with their treatment with amiodarone. |
| **2.** | Take amiodarone tablets as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist. |
| **3.** | Inform the GP and specialist if pregnant or planning a pregnancy. |
| **4.** | Following acceptance of shared care of prescribing by the GP, obtain further prescriptions for amiodarone tablets from the GP and not the specialist. |
| **5.** | Inform their GP of any over the counter products and inform the community pharmacist that they are prescribed amiodarone when buying over the counter medications. |
| **6.** | Avoid grapefruit juice while taking amiodarone and for several months after discontinuation. |
| **7.** | Use appropriate self-care against the possibility of phototoxic reactions: e.g. sun avoidance, protective clothing, avoiding tanning (including tanning beds) and to purchase and use a broad spectrum sunscreen (at least SPF30). These measures to be continued for the duration of therapy and for several months after discontinuation. |
| **8.** | If taking a statin and amiodarone, to report any signs of unexplained muscle pain, tenderness, weakness or dark coloured urine. |
| **9.** | Moderate alcohol intake to no more than 14 units per week to reduce the risk of hepatotoxicity. |
| **10.** | Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop:   * Breathlessness, non-productive cough or deterioration in general health (e.g. fatigue, unplanned weight loss or gain, fever, heat and cold intolerance). * New or worsening visual disturbances. * Progressive skin rash +/- blisters or mucosal lesions. * Signs and symptoms of bradycardia or heart block, e.g., dizziness, fatigue, fainting, shortness of breath, chest pain or palpitations, confusion or trouble concentrating. |
| **11.** | Attend for monitoring and review appointments with GP (and specialist) as requested; if patients miss monitoring/appointments, GPs may be unwilling to continue to supply amiodarone. |

**DISPENSING PHARMACIST RESPONSIBILITIES**

* Confirming that the patient has received verbal and written patient counselling / information and provide additional counselling should this be required.
* Check the patient is being monitored regularly to ensure that it is safe before issuing or dispensing prescriptions.

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| **MONITORING AND ACTIONS TO BE TAKEN**  Refer to pages 2 - 3. |

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| **SIDE EFFECTS AND ACTIONS TO BE TAKEN (REFER TO** [**BNF**](https://bnf.nice.org.uk/drugs/amiodarone-hydrochloride/) **AND** [**SPC**](https://www.medicines.org.uk/emc/product/13964/smpc) **for full details)**   * GP to liaise with specialist if any side effects are a cause for concern. * Any serious adverse reactions should be reported to the MHRA via the Yellow Card scheme. Visit www.mhra.gov.uk/yellowcard * For information on incidence of ADRs see relevant summaries of product characteristics * The most serious toxicity with amiodarone is seen with long-term use. Due to the long half-life of amiodarone, there is potential for adverse effects to occur for several weeks/months after treatment has been discontinued.  |  |  | | --- | --- | | **SIDE EFFECTS** | **Action to be taken by GP** | | **Ophthalmological effects:** |  | | Optic neuropathy/neuritis;  blurred or decreased vision | **Stop amiodarone.** Urgent referral to initiating specialist and ophthalmology. | | Corneal micro-deposits:  blueish halos when looking at bright lights, with no blurred or decreased vision | Continue amiodarone, reversible on discontinuation. The deposits are considered essentially benign and do not require discontinuation of amiodarone. | | **GI disturbance**: nausea, anorexia, vomiting, taste disturbance | Continue amiodarone. May require dose reduction; discuss with specialist if persistent. | | **Neurological symptoms:**  Extrapyramidal tremor, ataxia, peripheral neuropathy, myopathy | Continue amiodarone. May require dose reduction; discuss with specialist. | | **Pulmonary toxicity:** including pneumonitis or fibrosis new/worsening cough, shortness of breath or deterioration in general health (e.g. fatigue, weight loss, fever) | **Stop amiodarone.** Urgent referral to initiating specialist and respiratory specialist. Admission may be required. | | **Bullous skin reactions:**  life threatening or even fatal cutaneous reactions Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN) | **Stop amiodarone.** Urgent referral to dermatology, inform initiating specialist | | Photosensitivity | Continue amiodarone. Reinforce appropriate self-care e.g. sun avoidance and purchasing of a broad spectrum sunscreen (at least SPF30). | | Skin discolouration (blue/grey):  occurs in unprotected, light exposed skin | Continue amiodarone. May require dose reduction; discuss with specialist.  Reinforce self-care measures (as for photosensitivity above). Pigmentation slowly disappears following treatment discontinuation | |

**CONTRAINDICATIONS AND PRECAUTIONS**  **(REFER TO** [**BNF**](https://bnf.nice.org.uk/drugs/amiodarone-hydrochloride/) **AND** [**SPC**](https://www.medicines.org.uk/emc/product/13964/smpc) **for full details)**

This information does not replace the Summary of Product Characteristics (SPC), and should be read in conjunction with it. Please see BNF & SPC or comprehensive information.

Contraindications:

* Sinus bradycardia and sino-atrial heart block/severe conduction disturbances (high grade AV block, bifascicular or trifascicular block) or sinus node disease (unless pacemaker fitted).
* History of thyroid dysfunction. Use of amiodarone may be considered in patients who are euthyroid, after case-by-case assessment of the risks and benefits and with appropriate monitoring.
* Known hypersensitivity to iodine or amiodarone, or any of the excipients (including patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption) Concurrent use with medicines that may prolong the QT interval or increase the risk of Torsades de Pointes.
* Pregnancy - Due to the risk of neonatal goitre, amiodarone should only be prescribed in pregnancy if there is no alternative. Under these circumstances prescribing and monitoring will be the responsibility of the initiating specialists.
* Breastfeeding

Cautions:

* Amiodarone can cause serious adverse reactions affecting the eyes, heart, lung, liver, thyroid gland, skin and peripheral nervous system; it is subject to a number of cautions.
* Because these reactions may be delayed, patients on long-term treatment should be carefully supervised.
* As undesirable effects are usually dose-related, the minimum effective maintenance dose should be given.

**NOTABLE DRUG INTERACTIONS (REFER TO** [**BNF**](https://bnf.nice.org.uk/drugs/amiodarone-hydrochloride/) **AND** [**SPC**](https://www.medicines.org.uk/emc/product/13964/smpc) **for full details)**

**•** The following list is not exhaustive. Please see BNF or SPC for comprehensive information and recommended management.

• Due to the long half-life of amiodarone, there is potential for drug interactions to occur for several weeks/months after treatment has been discontinued. See SPC for information on managing interactions.

• Amiodarone is associated with many interactions, some of which are significant enough to contraindicate concurrent use, require dose adjustment and/or additional monitoring.

Amiodarone is an enzyme inhibitor and can increase exposure to several medicines including:

• P-glycoprotein (PgP) substrates (e.g. digoxin, dabigatran)

• CYP2C9 substrates (e.g. warfarin, phenytoin)

• CYP3A4 substrates (e.g. ciclosporin, statins, fentanyl, sildenafil, colchicine)

• CYP2D6 substrates (e.g. flecainide)

Amiodarone interacts with other medicines that:

• Induce Torsade de Points or prolong QT (e.g. other anti-arrhythmics, antipsychotics, antidepressants, clarithromycin, erythromycin)

• Lower heart rate (e.g. beta-blockers, calcium channel blockers)

• Induce hypokalaemia (e.g. diuretics, stimulant laxatives)

• Induce hypomagnesaemia (e.g. diuretics, systemic corticosteroids)

Other interactions include:

• CYP3A4 and CYP2C8 inhibitors: may increase exposure to amiodarone (e.g. cimetidine, letermovir, ritonavir, darunavir, grapefruit juice)

• Sofosbuvir with daclatasvir; sofosbuvir and ledipasvir; simeprevir with sofosbuvir: risk of severe bradycardia and heart block (mechanism unknown) see MHRA advice

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| **CONTACT DETAILS for BACK-UP INFORMATION / ADVICE**  **East and North Hertfordshire NHS Trust**   |  |  |  |  | | --- | --- | --- | --- | | **Department** | **Specialist Team designated nhs.net email** | **Pharmacy Team shared care admin contact** | **Out of hours contact / switchboard** | | **Cardiology** | [enh-tr.cardiologycdh@nhs.net](mailto:enh-tr.cardiologycdh@nhs.net) | [sharedcare.enh-tr@nhs.net](mailto:sharedcare.enh-tr@nhs.net)  01438 284 032 | 01438 314333 |   **West Hertfordshire Hospitals NHS Trust**   |  |  |  |  | | --- | --- | --- | --- | | **Department** | **Contact Number** | **Specialist Team designated nhs.net email** | **Out of hours contact / switchboard** | | **Cardiology** | 01923 436 403 | [westherts.cardio@nhs.net](mailto:westherts.cardio@nhs.net) | WGH:  01923 244 366  HHGH: 01442 213 141  SACH: 01727 866 122 |   **Princess Alexandra Hospital NHS Trust**   |  |  |  |  | | --- | --- | --- | --- | | **Department** | **Contact number** | **Specialist Team designated nhs.net email** | **Out of hours contact / switchboard** | | **Cardiology** | 01279 827203/ 01279 827337 | [tpa-tr.cardiologyadminclinicalcorrespondence@nhs.net](mailto:tpa-tr.cardiologyadminclinicalcorrespondence@nhs.net) | 01279 444 455 |   **Communication**  For any queries relating to a patient’s treatment with amiodarone, please contact the specialist as documented at the top of this document. Read in conjunction with [Hertfordshire and West Essex Area Prescribing Committee (HWE APC) shared care principles](https://www.hweclinicalguidance.nhs.uk/all-clinical-areas-documents/download?cid=1739&checksum=752d25a1f8dbfb2d656bac3094bfb81c). For advice if you have any concerns contact the specialist team. If unable to contact specialist team or out of hours, contact medical registrar on call. |

**REFERENCES**

* National Institute for Health and Care Excellence (NICE)) (2021), NICE guideline [NG196]. Atrial fibrillation: diagnosis and management. Available at: https://www.nice.org.uk/guidance/ng196/resources/atrial-fibrillation-diagnosis-and-management-pdf-66142085507269 (Accessed: 10/05/2024)
* BNF Joint Formulary Committee. BNF (online) London: BMJ Group, Pharmaceutical Press, and RCPCH Publications (Accessed 10/05/2023)
* Electronic Medicines Compendium (emc), SmPC Amiodarone. Available at: https://www.medicines.org.uk/emc/product/13964/smpc (Accessed: 10/05/2024).
* NHS Shared Care Protocols (SCPs), Amiodarone for patients within adult services. Available at: NHS England » Shared Care Protocols (SCPs) (Accessed 10/05/2024)
* NHS England (NHSE) and NHS Clinical Commissioners’ (NHSCC) policy guidance: Items which should not routinely be prescribed in primary care.

**GP Considerations for Shared Care**

This shared care agreement outlines suggested management for the prescribing of the specified drug(s) and indication(s) when the responsibility is shared between the specialist and general practitioner (GP). Sharing of care assumes communication between the specialist, GP and patient. It is important that patients are consulted about treatment and are in agreement with it. The intention to share care should be explained to the patient by the doctor initiating treatment and consent obtained.

Prescribing is to be initiated in secondary care by a provider Trust specialist and will usually be prescribed for 12 weeks unless otherwise stated within the agreed individual shared care protocol**. The expectation is that these shared care guidelines should provide sufficient information to enable GPs to be confident to take on the clinical and legal responsibility for the prescribing and the monitoring of this / these drug(s) in stable patients.** The questions below will help you confirm this:

* Is the patient’s condition predictable or stable?
* Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care document?
* Have you been provided with relevant clinical details including monitoring data?
* Have this document and BNF/SPC provided sufficient information for you to feel confident in accepting clinical and legal responsibility for prescribing?

**If you can answer YES to all of these questions (after reading this shared care guideline), then it is appropriate for you to accept the prescribing responsibility. GPs need to formally accept shared care by completing and returning the form provided within this protocol to the specialist within two weeks of receipt of request to share care.**

If the answer is NO to any of these questions, you should not accept prescribing responsibility. You should respond back to the consultant outlining your reasons for NOT prescribing on the agreement form within two weeks of receiving the request to share care. If you do not have the confidence to prescribe, you still have the right to decline. In such an event, the total clinical responsibility for prescribing the medication and any monitoring required remains with the specialist. Please note that medication cost is not an acceptable reason for refusal to take on shared care.

The prescribing doctor legally assumes clinical responsibility for the drug and the consequences of its useas well as responsibility of monitoring (securing and reviewing blood test results).

Prescribing and monitoring responsibility will only be transferred when the consultant and the GP agree that the patient’s condition is stable or predictable. This will usually be 12 weeks of treatment unless otherwise stated within the agreed individual shared care protocol.

**Approval Information**

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| Title of Guideline | Amiodarone tablets for adults used for tachyarrhythmias associated with Wolff-Parkinson-White Syndrome, Atrial Flutter Fibrillation / Atrial Fibrillation, Paroxysmal Tachyarrhythmias and Ventricular Fibrillation when other drugs cannot be used as well as for prior and post Cardioversion or in specific patients who have Heart Failure or Left Ventricular Impairment. Shared Care Protocol |
| Guideline Number | 17 |
| Version | 1.1 Updated with wording on swallowing difficulties and patient consent to shared care. September 2024 |
| Effective Date | June 2024 |
| Review Date | This shared care guidance will be reviewed upon request in the light of new evidence becoming available |
| Original Version Produced | N/A |
| ***Approvals:*** |  |
| Provider Trust Drug / Formulary Management Group (e.g. MUSP, TPC) | HWE ICB |
| HWE APC | June 2024 |
| Author/s | HWE ICB Pharmacy and Medicines Optimisation Team |
| Department(s) responsible for updating the guideline | HWE ICB Pharmacy and Medicines Optimisation Team |