SHARED CARE ARRANGEMENT AND PRESCRIBING INFORMATION FOR AMIODARONE (adults only)

N.B. This document should be read in conjunction with the current Summary of Product Characteristics (SmPC).

Patient safety is paramount. The prescriber who prescribes the medicine legally assumes clinical responsibility for the drug and the consequences of its use.

GENERIC AND BRAND NAME (formulations and strength)

Name: Amiodarone

Formulation: Tablets

Strength: 100mg and 200mg

STATUS OF MEDICINE

Licence status: POM, Licensed.

Formulary status: Amber 1

Black triangle medicine: Yes ☐ No ☒

Risk minimisation materials (RMM): Yes ☐ No ☒

CONDITION(S) TO BE TREATED

Cardiac arrhythmias, under specialist cardiology electrophysiology advice.

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.

TYPICAL DOSAGE REGIME	
Licensed dose	200mg three times daily for 7 days, then twice daily for 7 days, then reduced to appropriate maintenance dose (typically ranging from 100-400mg once daily) thereafter.
Route of administration	oral
Recommended starting dose	200mg three times daily (see above).
Titration dose/increment	Dosing may be adjusted depending on the clinical need of the patient.
Maximum dose	Usual maximum daily maintenance dose is 400mg.
Situations requiring dose adjustment	The dose should be adjusted to the minimum necessary to control the cardiac arrhythmia.
Duration of treatment	Varies depending on clinical condition (e.g. 6-8 weeks post cardiac surgery, until successful DCCV/ablation up to lifelong).

RESPONSIBILITY OF ACUTE CARE/SPECIALIST SERVICE

- Baseline:
    - Thyroid function tests; liver function tests (LFTs) and U&Es.
    - All patients should have a baseline chest X-ray and ECG.

Before starting amiodarone:

- If respiratory symptoms (e.g. cough, breathlessness) arrange clinical assessment and consider spirometry/gas transfer. Consider an alternative anti-arrhythmic drug or discuss with a respiratory physician if the chest X-ray suggests pre-existing fibrotic change.If asymptomatic, not essential to perform spirometry/gas transfer, unless clinician considers patient "high risk", e.g. daily dose 400mg/day or greater or if concern about underlying respiratory diseases.

- Copy of results to be sent to primary care clinician/continuing prescriber.

- Initiation of therapy and recommendations for dose increments ensuring the patient is aware of required monitoring and side effects to report.

- Decision on final dose required for patient.

- Monitoring clinical response to treatment.

- If new respiratory symptoms develop while using amiodarone (e.g. cough or breathlessness) arrange an urgent chest X-ray and lung function tests including where possible gas transfer factor. An HRCT may be required to help confirm or refute the development of pneumonitis.

- If optic neuropathy suspected arrange ophthalmological examination.

- If thyroid toxicity suspected, discuss and liaise with consultant endocrinologist as appropriate.

ADMINISTRATIVE RESPONSIBILITIES OF PRIMARY CARE

A practice agreeing to prescribe amiodarone should:

- Ensure that the relevant monitoring requirements are undertaken at the correct frequency.
- Ensure that the test results are checked for any abnormality as soon as the results are available.
- Ensure abnormal results are acted upon promptly (see Common Side Effects and Their Management).
- Contact the GP/consultant in the event of a drug reaction, monitoring abnormality, or if you are concerned in any way regarding the current treatment regime.

CLINICAL CARE WHICH IS THE RESPONSIBILITY OF THE PRESCRIBING CLINICIAN

- Prescribe medication under guidance of consultant.
- Check before prescribing each instalment of medication that the monitoring is up to date and that results are within the normal range.
- Ensure that the relevant monitoring parameters are undertaken at the correct frequency.
- Conduct recommended laboratory tests and contact hospital consultant to advise if results are out with range
    - Clinical assessment of thyroid status combined with thyroid function tests and LFTs every 6 months and for up to 8 months after discontinuing therapy.
- Ensure no interacting medications are prescribed in primary care (See SmPC for full details).
- Monitor for concordance with therapy.
- Report any adverse events to consultant and the MHRA using the Yellow Card System.
- When writing laboratory request forms always include details of the patient's medication.

Note: In addition to absolute values for haematological or biochemical indices a rapid change or a consistent upward/downward trend in any value should prompt caution and extra vigilance.

If something unexpected occurs contact consultant. Notify the consultant if the drug is stopped.

RESPONSIBILITY OF OTHER HEALTHCARE PROFESSIONALS

N/A.

RESPONSIBILITY OF THE PATIENT

Take medication regularly as directed by the specialist/doctor.

Attend hospital and GP clinic appointments as requested by specialist/GP practice. Failure to attend appointments may result in medication being reviewed/stopped.

Report any adverse effects/illness to the specialist/GP and present rapidly to specialist/GP should their condition significantly worsen

PRESCRIBING INFORMATION

For specific product information consult the current summary of product characteristics(http://emc.medicines.org.uk/),the BNF/BNF for Children(https://www.medicinescomplete.com/mc/index.htm)

CONTRAINDICATIONS

- 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.
- The combination of amiodarone with drugs which may induce Torsades de Pointes.
- Pregnancy - except in exceptional circumstances.
- Lactation.

PREGNANCY

There are insufficient data on the use of amiodarone during pregnancy in humans to judge any possible toxicity.

However, in view of its effect on the foetal thyroid gland, amiodarone is contraindicated during pregnancy, except in exceptional circumstances.

If, because of the long half-life of amiodarone, discontinuation of the drug is considered prior to planned conception, the real risk of reoccurrence of life threatening arrhythmias should be weighed against the possible hazard for the foetus.

Adequate contraception should therefore be used during and for 8 months after treatment discontinuation.

BREAST-FEEDING

Amiodarone is excreted into the breast milk in significant quantities and breast-feeding is contraindicated.

COMMON SIDE EFFECTS AND THEIR MANAGEMENT

Any newly developed hypo or hyperthyroidism should be discussed by the consultant cardiologist, and if necessary, consultant endocrinologist. Both should be involved in the decision regarding future treatment options.

Severe liver function abnormalities, or clinical signs of liver disease. Note that amiodarone may be associated with a variety of hepatic effects including cirrhosis, hepatitis and jaundice. At the beginning of therapy, elevation of serum transaminases (1.5 to 3 times normal) may occur. These may return to normal with dose reduction, or sometimes spontaneously. These should be discussed with consultant cardiologist, and if appropriate, liver specialist team.

Pulmonary Toxicity. Patients should be asked about the development of new or progressive shortness of breath, non-productive cough, or deterioration in general health at each visit. Persistent (>2 weeks) respiratory symptoms should prompt clinical assessment, discussion with the hospital consultant and a repeat chest X-ray/detailed pulmonary function tests, including transfer factor where possible.

Amiodarone sensitises the skin to sunlight, patients can burn very easily. Exposure to direct sunlight also produces pigmentation of the skin, which can be permanent. To minimise the photosensitivity reactions exposure to sunlight and ultraviolet light should be limited by wearing protective clothing and using sunscreen with a high protection factor.

Ophthalmological Reactions. Patients on continuing therapy always develop micro-deposits in the cornea. This is usually of no clinical consequence and may rarely cause subjective symptoms such as visual haloes in dazzling light (especially at night) and blurring vision. Patients should be warned of this and cautioned regarding potential effect on driving and the performance of skilled tasks. Optic neuropathy is rare and usually presents as decreased or blurred vision – if this occurs, patient should discussed urgently with the Clinical Decision Unit at the Eye Clinic, Aberdeen Royal Infirmary.

COMMON DRUG INTERACTIONS (for a full list see SmPC)

- Amiodarone is highly protein bound and has a very long half-life (on average 50 days), monitoring should be continued for up to 8 months after discontinuing therapy

- Some of the important drugs that interact with amiodarone include warfarin, digoxin, phenytoin, and drugs which prolong the QT interval.
- Amiodarone can significantly increase the International Normalised Ratio (INR) suddenly; therefore the INR should be monitored very closely for two weeks following the addition of amiodarone to existing warfarin therapy.
- If amiodarone and warfarin are started concurrently a warfarin dose reduction of approximately one third should be considered along with close monitoring of the INR.
- On discontinuation of amiodarone the INR may be significantly reduced and therefore INR should be monitored closely.
- Phenytoin plasma levels should be monitored and dosage should be reduced if toxicity occurs.
- Drugs that prolong the QT interval are contra-indicated (check SmPC for full list and refer to https://www.crediblemeds.org/index.php/login/dlcheck website).
- The dose of simvastatin should not exceed 20mg daily in patients receiving concomitant medication with amiodarone, due to the increased risk of myopathy and rhabdomyolysis.
- Grapefruit juice should be avoided.
- Caution should be given to concurrent medications which may cause hypokalaemia, and adequate monitoring performed.

ADVERSE DRUG REPORTING

If an adverse reaction should occur inform relevant medical practitioner as soon as possible.

Report to the MHRA using the Yellow Card System https://yellowcard.mhra.gov.uk/

REFERENCES

1. Electronic Medicines Compendium (eMC), 2017. Amiodarone 200mg tablets [online] Available at: Amiodarone 200mg Tablets - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) [Last updated 17th May 2017; Accessed 3rd June 2021].

ACUTE CARE/SPECIALIST SERVICE CONTACT INFORMATION

In the event of a concern being raised, the primary care practitioner should contact the referring consultant via the hospital switchboard, via their secretary, by e-mail or letter, whichever is more appropriate. If the concern is urgent, and out of hours advice is required, the on call Cardiology Specialist Registrar may be contacted via switchboard.

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