Pan Mersey
Area Prescribing Committee

Prescribing Support Information

AMIODARONE

AMBER patient retained by specialist

Your patient has been identified as being suitable to receive amiodarone in accordance with the indications detailed below. They have been started on treatment and have been reviewed to assess the efficacy and adverse effects of the treatment by the specialist team.

Amiodarone has been considered as appropriate for prescribing in primary care and the information contained in this document has been provided to support you to prescribe it for your patient in the community. Your patient's dose is now stable and is detailed in the attached clinic letter.

Your patient will remain under the care of the specialist team whilst receiving amiodarone.

Guidance from NHS England
Amiodarone has an important place in the treatment of severe cardiac rhythm disorders where other treatments either cannot be used or have failed. It has potential major toxicity and its use requires monitoring both clinically and via laboratory testing[1].

If, in exceptional circumstances, there is a clinical need for amiodarone to be prescribed, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional. It must be initiated by a specialist and only continued under a local agreement for patients where other treatments cannot be used, have failed, or is in line with NICE Guidance CG180. It may also be suitable in patients prior and post cardioversion or in specific patients who also have heart failure or left ventricular impairment.

Indications

- Severe rhythm disorders not responding to other therapies or when other treatment cannot be used.
- Tachyarrhythmias associated with Wolff-Parkinson-White syndrome.
- 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.

Drug, Form and Dose
Amiodarone tablets 100mg and 200mg

Amiodarone suspension (unlicensed special) 10mg/ml

Adults:
The minimum effective dose should be used. Treatment should be started with 200mg, three times a day then titrated down to a maintenance dose of 200mg daily, or less if appropriate.

Rarely, the patient may require a higher maintenance dose. The maintenance dose should be regularly reviewed, particularly if it exceeds 200mg daily.

Whilst there is no evidence that dosage requirements are different for elderly patients, they may be more susceptible to bradycardia and conduction defects if too high a dose is prescribed. Particular attention should be paid to monitoring thyroid function.

Children:
The safety and efficacy of amiodarone in children has not been established. Not licensed for children under 3 years.

Age 1 month -11 years: After dose titration, 5–10 mg/kg once daily; maximum 200 mg per day.

Age 12-17 years: After dose titration, usually 200mg daily adjusted according to response.

Monitoring recommendations

- The specialist should perform an ECG prior to starting treatment and this should be repeated annually by the specialist**.**
- A chest X-ray should be performed before starting treatment.
- U&Es should be carried out before starting treatment.
- TFTs and LFTs should be carried out at baseline and then repeated every 6 months by the GP.
- If blurred or decreased vision occurs, a complete ophthalmologic examination including fundoscopy should be promptly performed. Unless blurred or decreased vision occurs, ophthalmological examination is recommended annually. This should be arranged by the specialist.

Due to the long half-life of amiodarone, clinical symptoms may occur several months after stopping the drug so monitoring 6 months after stopping is recommended.

How long the medicine should be prescribed for
The specialist will determine the duration of treatment. The GP should be informed after every annual review if ongoing treatment remains appropriate.

Contra-indications

- Sinus bradycardia and sino-atrial heart block: In patients with severe conduction disturbances or sinus node disease, amiodarone should be used only in conjunction with a pacemaker.
- Evidence of history of thyroid dysfunction.
- Known hypersensitivity to iodine or to amiodarone.
- The combination of amiodarone with drugs which may induce Torsades de Pointes.
- Pregnancy - except in exceptional circumstances and lactation.

Adverse effects
Amiodarone can cause serious adverse reactions affecting the eyes, heart, lung, liver, thyroid gland, skin and peripheral nervous system. 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. Please see the Summary of Product Characteristics for a complete list.

Seek advice from the initiating specialist if there are any concerns about adverse effects.

Special warnings/cautions
Appearance of optic neuropathy and/or optic neuritis requires amiodarone withdrawal due to the potential progression to blindness.

Patients should be warned to report increased SOB or cough and amiodarone should be stopped if possible whilst this is investigated. Pulmonary toxicity occurs in around 2% of people taking amiodarone.

Interaction with other medicines
Numerous drugs interact with amiodarone. For full details please see the Summary of Product Characteristics.

Referral back to the specialist
Existing patients who have been discharged by the specialist: The GP should continue to prescribe amiodarone with consideration of referral back to the specialist.

Patients under the care of a specialist should have an annual review which includes an ECG, ophthalmological examination and assessment of the need for ongoing treatment.

Please contact the specialist team if any of the following occur:

- Development of blurred or decreased vision or changes in visual acuity
- Development of breathlessness – a chest X-ray may be required.
- Any new neurological signs e.g. pins and needles, numbness, burning or sharp pain, muscle weakness or cramps.
- Abnormal TFT or LFT.
- If the patient suffers any other adverse reactions.
- If the patient decides to discontinue treatment for any reason.
- Any deterioration in symptoms should be reported to the specialist team.

Contact details for advice
Please refer to the contact details included in the clinic letter issued by the specialist.

References

1. Items which should not routinely be prescribed in primary care: Guidance for CCGs Version 2, June 2019 items-which-should-not-routinely-be-prescribed-in-primary-care-v2.1.pdf
2. Summary of Product Characteristics. SPC