Hartlepool and Stockton-on-Tees Clinical Commissioning Group
South Tees Clinical Commissioning Group
Hambleton, Richmondshire and Whitby Clinical Commissioning Group
South Tees Hospitals NHS
NHS Foundation Trust

Shared care guidelines

Drug	**Dronedarone**
Specialty	Cardiology
Indication	Dronedarone is indicated for the maintenance of sinus rhythm after successful cardioversion in adult clinically stable patients with paroxysmal or persistent atrial fibrillation (AF).
Overview	Dronedarone is an oral anti-arrhythmic drug. It is similar in structure and function to amiodarone. However, unlike amiodarone, it does not contain iodine and is therefore free of the many adverse effects associated with this. Recent evidence suggests it is associated with an increased risk of heart failure and liver toxicity.

Hospital specialist's responsibilities

Initial investigations:	As appropriate to clinical application. Include ECG monitoring, BP, HR, U&Es, creatinine, eGFR, & LFTs before prescribing.
Initial regimen:	400mg twice daily with morning and evening meal.
Clinical monitoring:	For adverse effects and management of AF.
Frequency:	Once monthly for first three months.
Safety monitoring:	BP, HR, U&Es, creatinine, eGFR, & LFTs. Check creatinine & LFTs 7 days after starting.
Frequency:	Check all parameters monthly for first three months. Patients should be advised to be vigilant for signs of heart failure, liver toxicity and pulmonary toxicity.
Prescribing arrangements:	Initiate/establish efficacy. Prescribing can be handed over to GP after minimum of 3 months.
Documentation:	Clinic letter, shared care document and monitoring results to GP.

GP's responsibilities

Maintenance prescription:	To take over prescribing after three months or as clinically appropriate for each patient. Dose adjustment of interacting drugs as appropriate.
Clinical monitoring:	For adverse effects and management of AF. Perform ECGs at least every 6 months. If AF recurs discontinuation should be considered – consult specialist with a view to stopping treatment.
Frequency:	At month 4, 5, 6, 9 and 12 and 6 monthly thereafter.
Safety monitoring:	BP, HR, U&Es, creatinine, eGFR, and LFTs
Frequency:	At month 4, 5, 6, 9 and 12 and annually thereafter. Patients should be advised to be vigilant for signs of heart failure, liver toxicity and pulmonary toxicity.
Duration of treatment:	Indefinite as recommended by specialist
Documentation:	Practice records. Correspondence with specialist

Adverse events

Adverse Event	Action required
Rise in creatinine of 10% or early after start of treatment	Expected in 10% of patients commenced on dronedarone. If this occurs use value as new reference baseline
Creatinine clearance < 30ml/min	Consult specialist with a view to stopping treatment (contraindicated)
Signs or symptoms of liver injury	Check LFTs – if ALT ≥ 3 x upper limit of normal remeasure within 48-72 hours. If raised levels confirmed withdraw dronedarone
Signs or symptoms of heart failure	Stop treatment (contraindicated)
Signs or symptoms of lung toxicity	Stop treatment (contraindicated)

Other information

Dronedarone is now contraindicated in patients with:

- Unstable haemodynamic conditions
- History of, or current, heart failure or left ventricular systolic dysfunction
- Permanent AF (ie, duration ≥6 months or unknown, and attempts to restore sinus rhythm no longer considered by physician)
- Liver and lung toxicity related to previous use of amiodarone

Dronedarone is primarily metabolised by cytochrome P450.
Dronedarone is contraindicated with Dabigatran.
Dronedarone is contraindicated with potent cytochrome P450 inhibitors and QT prolonging drugs e.g phenothiazines, azole antifungals, clarithromycin and tricyclic antidepressants.

Other clinically significant interactions include:
Statins – increased risk of statin toxicity – reduce statin dose (maximum dose of simvastatin 20mg daily and atorvastatin 20mg daily)
Beta-blockers – increased exposure to some beta-blockers; close monitoring required
Verapamil and diltiazem – increased risk of bradycardia and myocardial depression; close monitoring required
Digoxin – increased exposure to digoxin; halve digoxin dose and monitor closely.
Grapefruit juice and St John's Wort – should be avoided

South Tees Hospitals NHS
NHS Trust

Shared care guidelines

Contact details

Name: GMC No:

Address:

Telephone No:

Further Information

Associated documents

See manufacturers SPC or BNF for more prescribing information

NICE guidance. TA197. Atrial fibrillation – dronedarone. August 2010

MHRA Drug Safety Update, Oct 2011

Approved: April 2019 Review Date: April 2021