

DRONEDARONE Drug Specific Monitoring Document



TARGET AUDIENCE	Board-wide
PATIENT GROUP	All patients aged 12 years and older taking Dronedarone

References

- British National Formulary (2024). *BNF / NICE*. [online] NICE. Available at: <https://bnf.nice.org.uk/>.
- Specialist Pharmacy Service (2021). *Medicines Monitoring*. [online] SPS - Specialist Pharmacy Service. Available at: <https://www.sps.nhs.uk/home/tools/drug-monitoring/>.
- Electronic Medicines Compendium (2019). *Home - electronic medicines compendium (emc)*. [online] Medicines.org.uk. Available at: <https://www.medicines.org.uk/emc>

Governance information for drug specific document

Lead Author(s):	Medicines Policy and Guidance Team
Endorsing Body:	Area Drug and Therapeutics Committee
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Responsible Person (if different from lead author)	Kirsty Macfarlane/Mark Russell

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Medication Name	DRONEDARONE
Actions by specialist clinician before initiation	<ul style="list-style-type: none"> • LFTs • ECG • U&Es • Serum magnesium, as per consultant <p><i>For all drugs, specialist clinicians should consider whether vaccination/exclusion of other contraindications (including active infection), is required and arrange as appropriate.</i></p>
DIS actions on starting treatment and following dose titration during initiation period	<ul style="list-style-type: none"> • serum creatinine <ul style="list-style-type: none"> ○ measure 7 days after initiation - if raised, measure again after a further 7 days and consider discontinuation if creatinine continues to rise • LFTs <ul style="list-style-type: none"> ○ 1 week after initiation of treatment ○ Monthly for 3 months
Ongoing monitoring in Primary Care once stable	<ul style="list-style-type: none"> • LFTs monthly for a further 3 months (up to 6 months in total) then every 3 months for a further 6 months. • Annually <ul style="list-style-type: none"> ○ U&Es ○ LFTs <p>Ongoing monitoring for heart failure and lung disease (including CXR and 6 monthly ECG) remains the responsibility of specialist clinician</p>
Action if monitoring is outside reference range	<p>Hepatic function</p> <ul style="list-style-type: none"> • If ALT levels are greater than 3 x the upper limit of normal, ALT levels should be re-measured within 48 to 72 hours. • After re-measure, if ALT levels are confirmed to be greater than 3 x the upper limit of normal <ul style="list-style-type: none"> ○ treatment with dronedarone should be withdrawn ○ Appropriate investigation and close observation of patients should continue until normalisation of ALT <p>Renal function during early treatment</p> <ul style="list-style-type: none"> • If an increase is observed, creatinine should be re-measured after another 7 days. • Further increases should prompt consideration of further investigation and treatment discontinuation
Actions to take if restarting medication after treatment break	<p>Actions needed may vary - consult specialist team for further guidance</p> <p>Patients should be referred by the specialist clinician to the drug initiation hub if re-titration or enhanced monitoring is required</p>

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CONSULTATION AND DISTRIBUTION RECORD	
Contributing Author / Authors	Kirsty Macfarlane, Mark Russell, Kendal Paterson, Katrina Maroni
Consultation Process / Stakeholders:	LMC, GP Sub-committee, Eimear Gordon, Anthony Carson, Richard Shearer, Rebecca Malley, Rosemary Beaton, Drug Initiation Service pharmacists, Acute specialist cardiology consultants and pharmacists.
Distribution	Acute specialist consultants and pharmacists, Senior primary care pharmacists, all individuals involved with the Drug Initiation Service, LMC and GP sub-committee

CHANGE RECORD			
Date	Lead Author	Change	Version

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