

Dofetilide Criteria for Use January 2021

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive dofetilide.

- Congenital or acquired long QT syndromes
- Baseline QT interval or QTc > 440 msec (500 msec in patients with ventricular conduction abnormalities e.g., bundle branch blocks or intraventricular conduction delays)
- Severe renal impairment (calculated creatinine clearance per Cockcroft-Gault using actual body weight < 20 ml/min)
- Patients receiving treatment with verapamil, cimetidine, trimethoprim (alone or in combination with sulfamethoxazole), ketoconazole, prochlorperazine, dolutegravir, megestrol, hydrochlorothiazide (alone or in combination with triamterene)
- Concomitant use with drugs that prolong the QT interval, or Class I or other Class III antiarrhythmic drug therapy

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria for dofetilide.

- Restricted to VA / VA Community Care Cardiology provider or other locally designated provider for initial prescription¹
 - Atrial fibrillation / atrial flutter (highly symptomatic²) in patients who require cardioversion to normal sinus rhythm
- OR**
- Maintenance of normal sinus rhythm in patients with highly symptomatic² atrial fibrillation/atrial flutter who have been converted to normal sinus rhythm

¹ If dofetilide is being initiated, re-initiated, or the dose increased, use is restricted to inpatient admission for appropriate monitoring and dose adjustments

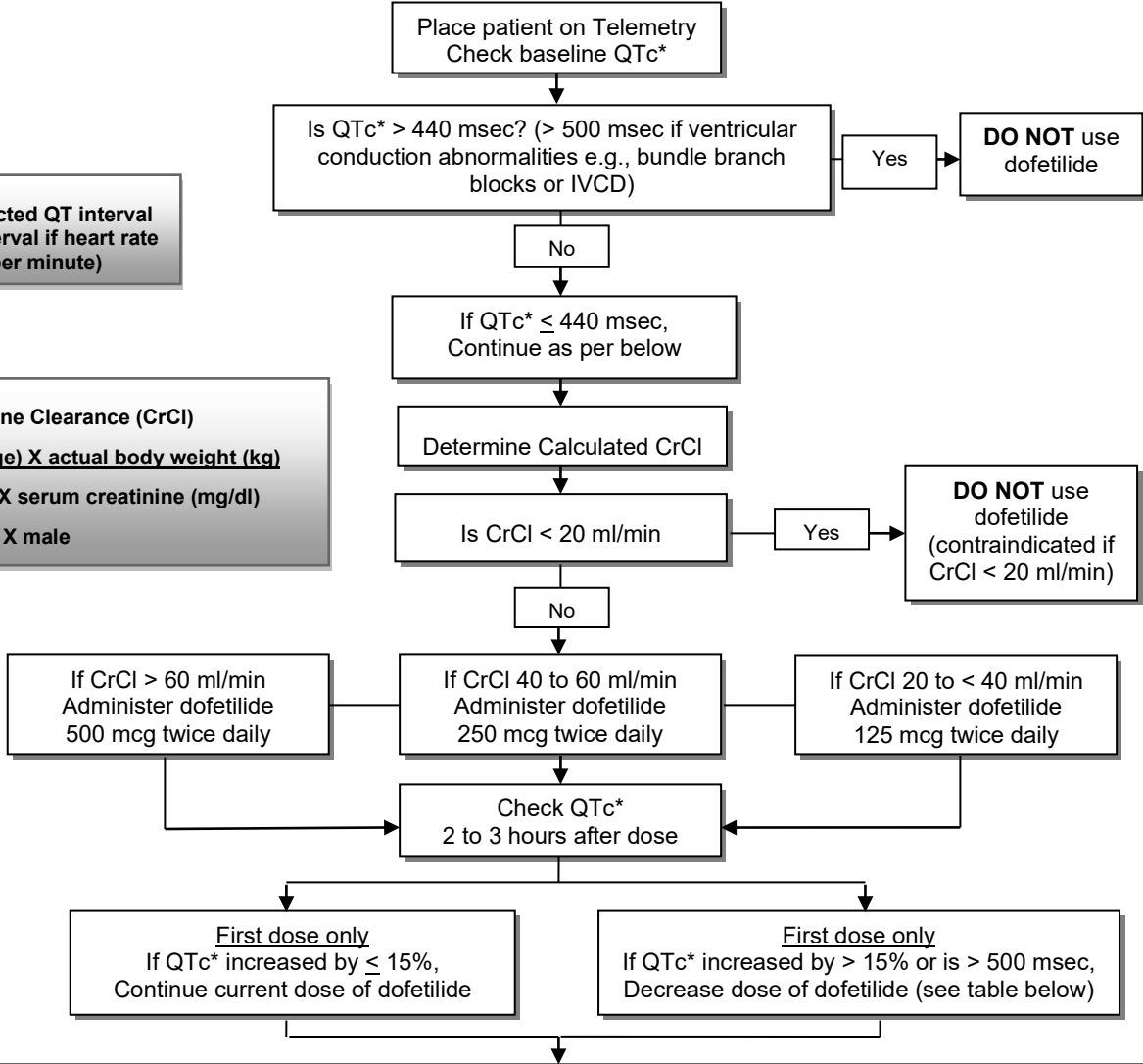
² Dofetilide can cause life threatening ventricular arrhythmias, it should be reserved for patients in whom atrial fibrillation / atrial flutter is highly symptomatic

Supplementary Information

Dofetilide Dosing Algorithm (Adapted from Dofetilide Prescribing Information)

*QTc: corrected QT interval
(use QT interval if heart rate < 60 beats per minute)

Calculated Creatinine Clearance (CrCl)
Male CrCl = (140-age) X actual body weight (kg)
72 X serum creatinine (mg/dl)
Female CrCl = 0.85 X male



Determine QTc* at 2 to 3 hours after each subsequent dose (for in hospital doses 2 to 5)
Dofetilide should be discontinued if at any time after the second dose the QTc* increases to > 500 msec (550 msec if ventricular conduction abnormalities e.g., paced rhythm [recommend treatment under direction of a Cardiologist with expertise in electrophysiology], bundle branch blocks or IVCD)
Continuous ECG monitoring should be conducted for a minimum of 3 days, or for a minimum of 12 hours after electrical or pharmacologic conversion to normal sinus rhythm, whichever is longer

Adjusted Dose if QTc* Prolongation (see above)
 [Note: only 1 down titration for QTc* suggested]

Starting Dose	Decreased Dose
500 mcg twice daily	250 mcg twice daily
250 mcg twice daily	125 mcg twice daily
125 mcg twice daily	125 mcg once daily