

Ivabradine (CORLANOR)

Criteria for Use

November 2022

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 UTILIZE 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 ivabradine.

- Acute decompensated heart failure
- Recent myocardial infarction (within the past 2 months)
- Cardiac resynchronization therapy started (within past 6 months)
- Atrial fibrillation or atrial flutter
- Congenital heart disease as etiology of heart failure
- Primary severe valvular heart disease as etiology of heart failure
- Clinically significant hypotension
- Sick sinus syndrome, sinoatrial block or 2nd or 3rd degree atrioventricular block, unless a functioning demand pacemaker is present
- Pacemaker with atrial or ventricular pacing (except biventricular pacing) greater than 40% of the time, or with stimulation threshold at the atrial or ventricular level at least 60 beats per minute (bpm)
- Family history or congenital long QT syndrome or treated with selected QT-prolonging agents
- Concomitant Class I antiarrhythmic agents
- Concomitant diltiazem or verapamil
- Concomitant strong or moderate CYP3A4 inhibitors, or CYP3A4 inducers
- Severe hepatic impairment (Child-Pugh C)

Inclusion Criteria

The answers to the following must be fulfilled in order to meet criteria for ivabradine.

- Care is provided by a VA / VA Community Care cardiologist or other locally designated provider for initial prescription

One of the following indications:

- Stable, symptomatic chronic heart failure with reduced left ventricular ejection fraction, ^1 on guideline directed medical therapy including a beta-blocker, ^2 with normal sinus rhythm and resting heart rate at least 70 bpm ^3

OR

- Symptomatic inappropriate sinus tachycardia with persistent symptoms despite treatment with a beta-blocker, or unable to use a beta-blocker

Additional Inclusion Criteria (Select if applicable)

For females of childbearing potential:

- For patients who can become pregnant: Counseling provided on potential risks vs. benefits of treatment and the use of effective contraception during therapy

1. New York Heart Association Class II to III heart failure with left ventricular ejection fraction 35% or less as per guideline recommendations
2. Beta-blocker at maximum tolerated dose, or unable to use a beta-blocker
3. Measured by 12 lead electrocardiogram after at least 5 minutes rest on 2 consecutive visits in pivotal clinical trial