









# CORLANOR® PRODUCT FACT SHEET





## INDICATION

Corlanor® (ivabradine) is indicated to reduce the risk of hospitalization for worsening heart failure in patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction  $\leq 35\%$ , who are in sinus rhythm with resting heart rate  $\geq 70$  beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.<sup>1</sup>

## PRODUCT INFORMATION

NDC	Description	Quantity
55513-800-60	  5mg tablets formulated as salmon-colored, oval-shaped, film-coated tablets scored on both edges, marked with "5" on one face and bisected on the other face	Bottle of 60 tablets
55513-800-80	  5mg tablets formulated as salmon-colored, oval-shaped, film-coated tablets scored on both edges, marked with "5" on one face and bisected on the other face	Bottle of 180 tablets
55513-810-60	  7.5mg tablets formulated as salmon-colored, triangular-shaped, film-coated tablets debossed with "7.5" on one face	Bottle of 60 tablets
55513-810-80	  7.5mg tablets formulated as salmon-colored, triangular-shaped, film-coated tablets debossed with "7.5" on one face	Bottle of 180 tablets



## STORAGE AND HANDLING REQUIREMENTS

Store at 25°C (77°F); excursions permitted to 15° - 30°C (59° - 86°F)

## PRODUCT EXPIRATION

The expiration date is printed on each bottle.

## SUPPLIED AND MARKETED BY

Amgen USA Inc.  
Phone 1-800-28-AMGEN (1-800-282-6436) • Fax 1-800-29-AMGEN (1-800-292-6436)  
www.amgen.com www.corlanorhcp.com

## PRODUCT RETURNS

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-844-6CORLANOR (844-626-7526). Credit for returns is subject to Amgen's current Returned Goods Policy.

## PRODUCT INFORMATION

Medical Information: 1-800-77-AMGEN (1-800-772-6436)

## COVERAGE INFORMATION

1-844-6CORLANOR (1-844-626-7526)

*Please see Important Safety Information on next page.*

## IMPORTANT SAFETY INFORMATION

- **Contraindications:** Corlanor<sup>®</sup> is contraindicated in patients with acute decompensated heart failure, blood pressure < 90/50 mmHg, sick sinus syndrome, sinoatrial block, 3<sup>rd</sup> degree AV block (unless a functioning demand pacemaker is present), a resting heart rate < 60 bpm prior to treatment, severe hepatic impairment, pacemaker dependence (heart rate maintained exclusively by the pacemaker), and concomitant use of strong cytochrome P450 3A4 (CYP3A4) inhibitors.
- **Fetal Toxicity:** Corlanor<sup>®</sup> may cause fetal toxicity when administered to a pregnant woman based on embryo-fetal toxicity and cardiac teratogenic effects observed in animal studies. Advise females to use effective contraception when taking Corlanor<sup>®</sup>.
- **Atrial Fibrillation:** Corlanor<sup>®</sup> increases the risk of atrial fibrillation. The rate of atrial fibrillation in patients treated with Corlanor<sup>®</sup> compared to placebo was 5% vs. 3.9% per patient-year, respectively. Regularly monitor cardiac rhythm. Discontinue Corlanor<sup>®</sup> if atrial fibrillation develops.
- **Bradycardia and Conduction Disturbances:** Bradycardia, sinus arrest and heart block have occurred with Corlanor<sup>®</sup>. The rate of bradycardia in patients treated with Corlanor<sup>®</sup> compared to placebo was 6% (2.7% symptomatic; 3.4% asymptomatic) vs. 1.3% per patient-year, respectively. Risk factors for bradycardia include sinus node dysfunction, conduction defects, ventricular dyssynchrony, and use of other negative chronotropes. Bradycardia may increase the risk of QT prolongation which may lead to severe ventricular arrhythmias, including torsades de pointes, especially in patients with risk factors such as use of QTc prolonging drugs.

Concurrent use of verapamil or diltiazem also increases Corlanor<sup>®</sup> exposure, contributes to heart rate lowering, and should be avoided. Avoid use of Corlanor<sup>®</sup> in patients with 2<sup>nd</sup> degree atrioventricular block unless a functioning demand pacemaker is present.

- **Adverse Reactions:** The most common adverse drug reactions reported at least 1% more frequently with Corlanor<sup>®</sup> than placebo and that occurred in more than 1% of patients treated with Corlanor<sup>®</sup> were bradycardia (10% vs. 2.2%), hypertension or increased blood pressure (8.9% vs. 7.8%), atrial fibrillation (8.3% vs. 6.6%), and luminous phenomena (phosphenes) or visual brightness (2.8% vs. 0.5%).

In postmarketing experience, torsades de pointes has been observed.

***Please see accompanying Full Prescribing Information and Medication Guide***

1. Prescribing Information, Corlanor<sup>®</sup>

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**AMGEN**<sup>®</sup>

Cardiovascular