

INDICATION

RAPIBLYK is indicated for the short-term reduction of ventricular rate in adults with supraventricular tachycardia including atrial fibrillation and atrial flutter.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

RAPIBLYK is contraindicated in patients with:

- Severe sinus bradycardia, sick sinus syndrome, heart block greater than first degree
- Decompensated heart failure
- Cardiogenic shock
- Pulmonary hypertension
- Hypersensitivity reactions to RAPIBLYK or any of the inactive ingredients

WARNINGS AND PRECAUTIONS

- Hypotension: Patients with hemodynamic compromise, hypovolemia, or on interacting medications are at increased risk of hypotension.
- Bradycardia: Patients with first-degree atrioventricular block, sinus node dysfunction, or conduction disorders are at increased risk of bradycardia, including sinus pause, heart block, severe bradycardia, and cardiac arrest.
- Cardiac Failure: Beta-blockers, like RAPIBLYK, can cause depression of myocardial contractility and may precipitate heart failure and cardiogenic shock.
- Reactive Airways Disease: Patients with reactive airways disease should, in general, not receive Beta blockers. Because of its relative beta-1 selectivity and titratability, RAPIBLYK injection may be titrated to the lowest possible effective dose.
- Patients with Diabetes Mellitus and Hypoglycemia: beta blockers may prevent early warning signs of hypoglycemia, such as tachycardia, and increase the risk for severe or prolonged hypoglycemia at any time during treatment, especially in patients with diabetes mellitus, patients who are fasting, or children.
- Infusion Site Reactions: Infusion site reactions such as pain, swelling and erythema have occurred with the use of RAPIBLYK.
- Patients with Prinzmetal's Angina: beta blockers may exacerbate anginal attacks.
- Patients with Pheochromocytoma: Administration of RAPIBLYK without opposing alpha blockade in the setting of pheochromocytoma has been associated with a paradoxical increase in blood pressure from the attenuation of beta receptor-mediated vasodilation in skeletal muscle.
- Patients with Peripheral Circulatory Disorders: RAPIBLYK may exacerbate peripheral circulatory disorders, such as Raynaud's disease or syndrome, and peripheral occlusive vascular disease.

- Severe exacerbations of angina, myocardial infarction, and ventricular arrhythmias have been reported in patients with coronary artery disease upon abrupt discontinuation of beta-blocker therapy.
- Beta-blockers, including RAPIBLYK, can cause increases in serum potassium and hyperkalemia. The risk is increased in patients with risk factors such as renal impairment.
- Patients with Metabolic Acidosis: Beta-blockers have been reported to cause hyperkalemic renal tubular acidosis.
- Patients with Hyperthyroidism: Beta-adrenergic blockade may mask certain clinical signs of hyperthyroidism.
- Patients at Risk of Severe Acute Hypersensitivity Reactions: may be more reactive to allergen exposure. Patients using beta blockers may be unresponsive to the usual doses of epinephrine used to treat anaphylactic or anaphylactoid reactions.

ADVERSE REACTIONS

The most important and common adverse reaction is hypotension, which in clinical trials occurred in 9.9% of patients receiving RAPIBLYK vs. 1% in those receiving placebo.

Please see the full Prescribing Information for Rapiblyk at

https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217202s000lbl.pdf