

Abridged Prescribing Information

Adenosine Solution for Intravenous Bolus Injection

ADENOCOR®

THERAPEUTIC CATEGORY

Antihypertensive

COMPOSITION

Each vial contains 6mg of adenosine per 2ml (3mg/ml).

THERAPEUTIC INDICATIONS: Rapid conversion into sinus rhythm of junctional tachycardia, including tachycardia associated with an accessory pathway (Wolff-Parkinson-White syndrome). Aid in the diagnosis of wide- or narrow-complex tachycardia. Although adenosine is not effective in the treatment of atrial flutter, atrial fibrillation and ventricular tachycardia, the slowing down of atrioventricular conduction can facilitate analysis of atrial activity. Sensitisation of intra-cavitary electrophysiological investigations.

DOSAGE AND ADMINISTRATION: Should be administered by rapid IV bolus. To be certain the solution reaches the systemic circulation, it should be administered either directly into a vein or into an IV line. If administered via an IV line, it should be injected as proximally as possible, and followed by a rapid saline flush. Not recommended in patients who develop high-level AV block at a particular dose. **Adults / Elderly:** Initial dose of 3mg administered in the form of a rapid IV bolus injection (over a 2 second period) followed by a rapid saline flush. If the first dose does not result in the elimination of supraventricular tachycardia within 1 to 2 minutes, a second 6mg dose should be given, followed by a rapid saline flush. And if second dose does not work within 1 to 2 minutes, 12 mg should be given, again as a rapid intravenous bolus injection. **Children (below 50 kg weight):** No controlled paediatric studies have been performed. The level of evidence does not allow a recommended posology. **Hepatic / Renal impairment :** As adenosine requires no hepatic or renal function for its activation or inactivation, hepatic and/or renal failure would not be expected to alter efficacy or tolerance.

SAFETY-RELATED INFORMATION

Contraindications: Contraindicated in patients having hypersensitivity to adenosine, sick sinus syndrome, second or third degree AV block (except in patients with a functioning artificial pacemaker), chronic obstructive lung disease (such as asthma), long QT syndrome, severe hypotension; decompensated states of heart failure.

Warnings: Adenosine should be used with caution in patients with left main coronary stenosis, uncorrected hypovolemia, stenotic valvular heart disease, left to right shunt, pericarditis or pericardial effusion, autonomic dysfunction or stenotic carotid artery disease with cerebrovascular insufficiency since it has potential to cause significant hypotension. Should be used with caution in patients with myocardial infarction, heart failure, or in patients with minor conduction defects that could be transiently aggravated during infusion in patients with atrial fibrillation or flutter and especially in those with an accessory bypass tract. Some cases of severe bradycardia reported in early post heart transplant patients; in the other cases, occult sino-atrial disease was present. Increased sensitivity of the heart to adenosine has been observed in patients with recent heart transplantation (less than 1 year). Adenosine may precipitate or aggravate bronchospasm. **PRECAUTIONS:** Adenosine is intended for use by physicians familiar with the product in a hospital setting with monitoring and cardio-respiratory resuscitation equipment available for immediate use if necessary. Administration should be discontinued immediately in case of angina, severe bradycardia, severe hypotension, respiratory failure (potentially fatal), or asystole/cardiac arrest (potentially fatal). In patients with history of convulsions/seizures, the administration of adenosine should be carefully monitored. If use of adenosine bolus injection is judged to be essential, dipyridamole should be discontinued 24 hours beforehand, or the dose of adenosine should be significantly reduced.

Pregnancy: Should not be used unless the physician considers the benefits to outweigh the potential risks. **LACTATION:** Contraindicated.

Adverse reactions: Very common and common adverse reactions are bradycardia, sinus pause, skipped beats, atrial extrasystoles, atrio-ventricular block, ventricular excitability disorders such as ventricular extrasystoles, non-sustained ventricular tachycardia, headache, dizziness, light-headedness, dyspnea, nausea, flushing, chest pressure/pain, feeling of thoracic constriction/oppression, burning sensation, apprehension.

For full prescribing information, please contact: Sanofi-Synthelabo (India) Private Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai 400072

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