For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

Primacor ® Injection
Milrinone Lactate Injection

COMPOSITION
Each ml of solution contains 1mg of milrinone as lactate salt.

THERAPEUTIC INDICATIONS
Indicated for the short-term treatment of severe congestive heart failure unresponsive to conventional maintenance therapy and for the treatment of patients with acute heart failure including low output states following cardiac surgery.

DOSAGE AND ADMINISTRATION: Adults :Loading dose : 50 micrograms/kg; administered slowly (over a period of 10 minutes). Maintenance dose 0.375 to 0.75 micrograms/kg/min. Children: Intravenous loading dose 50 to 75 µg/kg administered over 30 to 60 minutes. Intravenous continuous infusion to be initiated on the basis of hemodynamic response.

SAFETY RELATED INFORMATION
Contraindications: Contraindicated in patients with hypersensitivity to milrinone or any of the excipients.
Warnings: In patients with severe obstructive aortic or pulmonary valvular disease, or hypertrophic subaortic stenosis Primacor should not be used in lieu of surgical relief of the obstruction. Use of Primacor is not recommended in patients in the acute phase of post myocardial infarction as there are no clinical studies. Therapeutic need must be weighed against potential risks in paediatrics. **Precautions:** Caution should be exercised in patients with hypotension prior to treatment, or those showing excessive decreases in blood pressure during treatment. Primacor should be administered with caution if prior vigorous diuretic therapy is suspected to have caused significant decreases in cardiac filling pressure. Fluid and electrolyte changes, as well as serum creatinine levels should be carefully monitored. Improvement in cardiac output and consequently, diuresis, may require reduction in the dose of a diuretic agent. Hypokaliemia should be corrected by potassium supplementation in advance of or during Primacor use. Patients should be closely monitored during infusion (heart rate, clinical state, electro-cardiogram, fluid balance, electrolytes and renal function (i.e. serum creatinine)). An increase in ventricular ectopy including non-sustained ventricular tachycardia has been observed in some patients. Possibility of an increased ventricular response rate in patients with uncontrolled atrial flutter / fibrillation. In these patients prior digitalisation or treatment with other agents to prolong atrio-ventricular node conduction time should be considered**.** No experience in controlled trials with infusions of milrinone for periods exceeding 48 hours. Careful monitoring of the infusion site should be maintained so as to avoid possible extravasation. *Renal impairment**:*** Dosage adjustment required.
P**regnancy:** Should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.
Lactation: No information is available to indicate whether milrinone is excreted in breast milk.
Adverse reactions: Common ones are headaches, ventricular ectopic activity, ventricular tachycardia (non sustained or sustained), supra-ventricular arrhythmias and hypotension.

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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