

High Quality, Consistent & Reliable Images¹⁻⁴



Mechanical activation with VIALMIX[®] delivers consistent activation from vial to vial

- Produces consistent size and number of microbubbles
- Contributes to predictable, quality images from study to study^{1,3}
- Minimizes operator error⁵

LUMINITY[®] is the only ultrasound enhancing agent with Mechanical Activation contributing to consistent image quality^{1,6,7}

The homogeneity of LUMINITY[®] microbubbles optimizes border delineation and detection of subtle changes in both structure and function¹⁻³

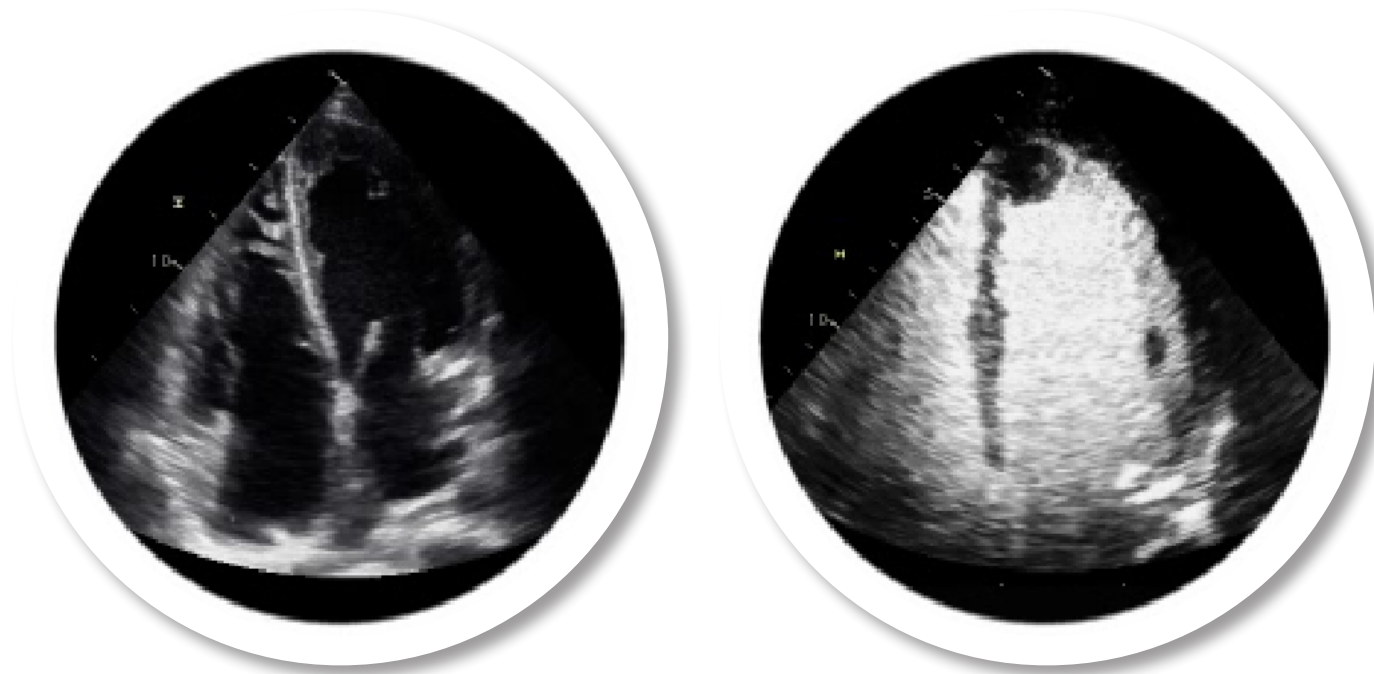


Unenhanced



LUMINITY[®]

LUMINITY[®] Improves Quality and Impacts Diagnostic Accuracy¹



Name: Luminity® 150 microlitres/ml gas and solvent for dispersion for injection/infusion. **Active Ingredient:** Perflutren. Each ml contains a maximum of 6.4×10^9 perflutren-containing lipid microspheres. The approximate amount of perflutren gas in each ml is 150 microlitres (μ l). **Therapeutic indications:** Luminity is an ultrasound contrast-enhancing agent for use in adult patients in whom non-contrast echocardiography was suboptimal and who have suspected or established coronary artery disease, at both rest and stress. **Posology and method of administration:** *Bolus intravenous injection using non-linear contrast imaging technique at rest and stress:* The recommended dose is multiple injections of 0.1 to 0.4 ml of dispersion, followed by a 3 to 5 ml bolus of sodium chloride 9 mg/ml (0.9%) or glucose 50 mg/ml (5%) solution for injection. The total dose of perflutren should not exceed 1.6 ml. *Bolus intravenous injection using fundamental imaging technique at rest:* The recommended dose is 10 microlitre dispersion/kg by slow bolus intravenous injection, followed by a 10 ml bolus of sodium chloride 9 mg/ml (0.9%) or glucose 50 mg/ml (5%) solution for injection. *Intravenous infusion using non-linear contrast imaging technique (rest and stress) or fundamental imaging technique at rest:* The recommended dose via an intravenous infusion is 1.3 ml dispersion added to 50 ml of sodium chloride 9 mg/ml (0.9%) or glucose 50 mg/ml (5%) solution for injection. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients (refer to SmPC). **Special warnings and precautions for use:** *Patients with unstable cardiopulmonary status:* Serious cardiopulmonary reactions, including fatalities, have occurred during or within 30 minutes of Luminity administration in patients including those with severe cardiac and pulmonary diseases. Extreme caution should be used when considering the administration of Luminity to patients with unstable cardiopulmonary status. *Patients with adult respiratory distress syndrome, endocarditis, prosthetic heart valves, systemic inflammation, sepsis, hyper-active coagulation and/or recurrent thromboembolism:* Luminity should be used only after careful consideration and such use should be monitored closely. *Patients with Pulmonary disease:* Caution should be exercised. *Patients with cardiac shunts:* The safety of Luminity in patients with right-to-left, bi-directional or transient right-to-left cardiac shunts has not been studied. Caution must be exercised. *Patients on mechanical ventilation:* The safety of microspheres has not been established. Caution should be exercised. **Fertility, pregnancy and lactation:** Caution should be exercised. **Undesirable effects:** The most frequently reported adverse reactions are: headache (2.0%), flushing (1.0%) and back pain (0.9%). Serious adverse events include: Allergic type reactions, anaphylaxis, anaphylactic shock and anaphylactoid type reactions, seizures, cardiac arrest, ventricular arrhythmias (ventricular fibrillation, ventricular tachycardia, premature ventricular contractions), asystole, atrial fibrillation, cardiac ischaemia, supraventricular tachycardia, supraventricular arrhythmia, dyspnoea, respiratory distress and rash. Prescribers should consult the Summary of Product Characteristics in relation to other adverse reactions. **Marketing Authorisation Holder:** Lantheus EU Limited
Marketing Authorisation Number(s): EU/1/06/361/001 – 002
Legal Category: Prescription Only Medicine – POM
Date: November 2019

Please see Summary of Product Characteristics. Available from your local representative and at <https://www.ema.europa.eu/en/medicines/human/EPAR/luminity>

Contact your local distributor for more information.