

## **LUMINITY<sup>®</sup> Has An Established Safety Profile with Extensive Safety Experience<sup>1,2</sup>**

- Across broad patient populations and in multiple care settings<sup>1-3</sup>
- Across gender and race in adults, including those age 65 and older<sup>1</sup>
- In patients with pulmonary hypertension<sup>4,5</sup>
- In patients with high prevalence of cardiopulmonary disease<sup>6</sup>



## A Proven Safety Profile

| Author               | Conclusion   | Journal  |
|----------------------|--|--|
| Main ML et al        | Associated with a 28% decreased risk of mortality at 48 h in critically ill patients                     | JACC Cardiovasc Imaging. 2014;7(1):40-48.            |
| Platts et al.        | No increased mortality in UEA patients   | Heart Lung Circ 2013;22:996-1002                     |
| Wei K et al          | No clinically important pulmonary/systemic hemodynamic or ECG changes in pulmonary hypertensive patients | J Am Soc Echocardiogr. 2012;25(5):584-588.           |
| Weiss RJ et al       | Well tolerated in patients with a high prevalence of cardiopulmonary disease                             | J Am Soc Echocardiogr. 2012;25(7):790-795.           |
| Wever-Pinzon O et al | Safe in hospitalized patients with PH  | Eur Heart J Cardiovasc Imaging. 2012;13(10):857-862. |
| Goldberg YH et al    | Not associated with increased acute mortality risk   | Cardiology. 2012;122(2):119-125.                     |
| Main ML et al        | Associated with a 24% decreased risk of mortality  | Am J Cardiol. 2008;102(12):1742-1746.                |
| Kusnetzky LL et al   | No increased mortality risk  | J Am Coll Cardiol. 2008;51(17):1704-1706.            |
| Nucifora G et al     | No significant change in vital signs in the first 24 h of MI   | Eur J Echocardiogr. 2008;9(6):816-818.               |
| Kitzman DW et al     | Well tolerated, provides LV cavity opacification, improves endocardial border delineation                | Am J Cardiol. 2000;86(6):669-674.                    |

## **A Proven Impact on Mortality Risk in the Critically Ill**

Comparison of 48-hour all-cause mortality among critically ill patients who underwent echocardiography with LUMINITY<sup>®</sup> to those without contrast in >1 million patients<sup>1</sup>

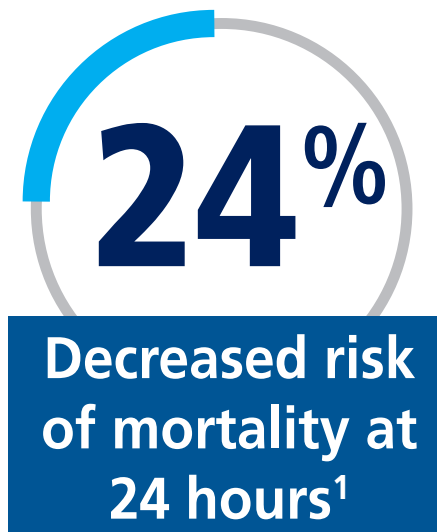
**LUMINITY<sup>®</sup> was associated with**



## **A Proven Impact on Mortality Risk in Hospitalized Patients**

Comparison of short term (1-day) mortality in hospitalized patients who underwent echocardiography with LUMINITY<sup>®</sup> to those without contrast in >4 million patients<sup>1</sup>

**LUMINITY<sup>®</sup> demonstrated**



**Name:** Luminity® 150 microlitres/ml gas and solvent for dispersion for injection/infusion. **Active Ingredient:** Perflutren. Each ml contains a maximum of  $6.4 \times 10^9$  perflutren-containing lipid microspheres. The approximate amount of perflutren gas in each ml is 150 microlitres ( $\mu$ 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.