Product Indication and Important Safety Information – OPTISON

INDICATIONS AND USAGE

OPTISON (Perflutren Protein-Type A Microspheres Injectable Suspension, USP) is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricle and to improve the delineation of the left ventricular endocardial borders.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS CARDIOPULMONARY REACTIONS

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration. Most serious reactions occur within 30 minutes of administration

- **Assess all patients for the presence of any condition that precludes OPTISON administration**
- **Always have resuscitation equipment and trained personnel readily available**

- **CONTRAINDICATION:** Do not administer OPTISON to patients with known or suspected hypersensitivity to perflutren or albumin.

- **WARNINGS AND PRECAUTIONS:** Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or shortly following administration. The risk for these reactions may be increased among patients with unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, or serious ventricular arrhythmias).

- Serious anaphylactic reactions have been observed during or shortly following perflutren-containing microsphere administration, including shock, hypersensitivity, bronchospasm, throat tightness, angioedema, edema (pharyngeal,palatal, mouth, peripheral, localized), swelling (face, eye, lip, tongue, upper airway), facial hypoesthesia, rash, urticaria, pruritus, flushing, and erythema have occurred in patients with no prior exposure to perflutren-containing microsphere products.

- When administering OPTISON to patients with a cardiac shunt, microspheres can bypass filtering of the lungs and enter the arterial circulation. Assess patients with shunts for embolic phenomena following OPTISON administration.

- High ultrasound mechanical index values may cause microsphere rupture and lead to ventricular arrhythmias. Additionally, end-systolic triggering with high mechanical indices has been reported to cause ventricular arrhythmias. OPTISON is not recommended for use at mechanical indices greater than
0.8.

- This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral disease.

- **ADVERSE EVENTS:** The most frequently reported adverse reactions in clinical trials were headache, nausea and/or vomiting, warm sensation or flushing and dizziness. Cardiac arrests and other serious but nonfatal adverse reactions were uncommonly reported in post-approval use. Reports also identified neurologic reactions (loss of consciousness or convulsions) as well as anaphylactoid reactions.

Please see the full Prescribing Information, including Boxed Warning for additional important safety information.

To report SUSPECTED ADVERSE REACTIONS, contact GE Healthcare at 800 654 0118 (option 2, then option 1), or the FDA at 800 FDA 1088 or www.fda.gov/medwatch