OPTISON (Perflutren Protein-Type A Microspheres Injectable Suspension, USP)

INDICATIONS:

OPTISON is an ultrasound contrast agent indicated for use in adult and pediatric patients with suboptimal echocardiogram to opacify to the left ventricle to improve the delineation of the left ventricle endocardial borders.

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**

CONTRAINDICATIONS:

OPTISON is contraindicated in 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 perflutren-containing microsphere administration, typically within 30 minutes of 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. OPTISON is only for intravenous administration; do not administer OPTISON by intra-arterial injection.
- 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.

Adverse Reactions

Common adverse reactions (incidence ≥ 0.5%) were: headache, nausea and/or vomiting, warm sensation or flushing, dizziness, dysgeusia, chills or fever, flu-like symptoms, malaise/weakness/fatigue, chest pain, dyspnea, injection site discomfort, and erythema. 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. Overall, the safety profile observed in pediatric patients from the clinical study was consistent with the safety profile in adult patients.

Use in Specific Populations

Pregnancy and Lactation:

There are no data with OPTISON use in pregnant woman to inform any drug-associated risks.

There are no data on the presence of perflutren protein-type A microspheres in human milk, the effects on the breastfed infant or the effects on milk production.

Pediatric Use

Safety and efficacy of OPTSON in pediatric patient is supported by evidence from adequate and well-controlled studies in adults and additional efficacy and safety data from a clinical study in 37 pediatric patients aged 9-17 years.

Geriatric Use

No overall differences in safety or effectiveness were observed in patients 65 years and over but a greater sensitivity to OPTISON in older individuals cannot be ruled out.

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 by email at GPV.drugsafety@gehealthcare.com or FDA at 800 FDA 1088 or www.fda.gov/medwatch