GE HealthCare

Choose Optison for safety, simplicity, and image quality in every vial.

Please scan the QR code to 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

IMPORTANT SAFETY INFORMATION ABOUT OPTISON

Indications and Usage
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 OPTISON 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.

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Reference: 1. Optison [prescribing information]. Marlborough, MA: GE HealthCare. 2025.

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July 2025 | JB11852US

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

GE HealthCare

Safety
Simplicity
Image Quality
in every vial

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

The ONLY Polyethylene Glycol (PEG) free ultrasound enhancing agent (UEA) in the US

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SAFETY

Reduce the risk of unpredictable PEG-related adverse reactions

THE ONLY PEG-FREE UEA, OPTISON supports diagnostic accuracy in echocardiography using a natural albumin shell for microbubbles that opacify cardiac echo images.

SIMPLICITY

Quick and easy resuspension for reliable access in the lab or on the go[1]

Mix Optison by hand in <60 seconds—no equipment required

Stable at room temperature for up to 24 hours[1]

If unopened, doses can be returned safely to storage at 2-8°C for later use[1]

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IMAGE QUALITY

Delivers consistent, high-quality diagnostic images

Recommended dosing by body weight in pediatric patients[1]

Body weight dose:

- 28 kg or less: 0.2 mL of Optison diluted with 0.2 mL of 0.9% Sodium Chloride Injection
- 29 kg to 40 kg: 0.3 mL of Optison diluted with 0.3 mL of 0.9% Sodium Chloride Injection
- 41 kg or more: 0.4 mL of Optison diluted with 0.4 mL of 0.9% Sodium Chloride Injection

Recommended administration for pediatric patients[1]

- Administer by intravenous injection at a rate not exceeding 0.05 mL/s
- If the contrast enhancement is inadequate after the initial dose, up to four additional doses of the same diluted volume
- May be repeated for further contrast enhancement as needed
- Optison must be diluted with 0.9% Sodium Chloride Injection to form a 1:1 dilution for pediatric administration

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