GE HealthCare Announces FDA Approval of Pediatric Indication for Optison Ultrasound Enhancing Agent

May 13, 2025

- *The latest approval will help provide clearer echocardiogram images for cardiologists to diagnose heart conditions in pediatric patients*
- *Optison is the only polyethylene glycol (PEG)-free ultrasound enhancing agent available in the U.S.*

ARLINGTON HEIGHTS, Ill.--(BUSINESS WIRE)--May 13, 2025-- GE HealthCare (Nasdaq: GEHC) today announced the U.S. Food and Drug Administration (FDA) has approved a pediatric indication for the company's Optison™ (Perflutren Protein-Type A Microspheres Injectable Suspension, USP) ultrasound enhancing agent (UEA). This approval will help improve the clarity and diagnostic accuracy of echocardiograms in pediatric patients, giving cardiologists a fuller picture of ventricular function when assessing possible heart abnormalities or disease.

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The U.S. FDA has approved GE HealthCare's Optison™ (Perflutren Protein-Type A Microspheres Injectable Suspension, USP) ultrasound enhancing agent for use in pediatric patients.

"In some pediatric patients, standard echocardiography cannot produce sufficiently clear images of the heart, potentially hindering cardiologists' ability to accurately diagnose underlying conditions," said Jit Saini, MD, Chief Medical Officer of the Pharmaceutical Diagnostics (PDx) segment of GE HealthCare. "This regulatory approval is a significant milestone that affirms the safety and efficacy of Optison in pediatric patients of all ages and expands our ability to offer this advanced imaging solution to a broader patient population. By facilitating more accurate measurement of left ventricular function, Optison enhances diagnostic capabilities, ultimately improving patient outcomes and providing greater value to healthcare providers and their patients."

Optison contains gas-filled microbubbles that reflect ultrasound waves more effectively than surrounding tissues or blood, making the heart chambers and endocardial borders more visible, which is necessary for assessing heart conditions. Optison has a proven safety profile established over decades and is the only UEA available in the U.S. that does not contain polyethylene glycol (PEG). This allows it to be safely used by patients with PEG hypersensitivity, as PEG carries the potential to trigger anaphylaxis or hypersensitivity reactions in some patients.

"Ultrasound enhancing agents have significantly advanced diagnostic quality in adult echocardiography over the years, and we are now seeing promising research supporting their safe and effective use in pediatric patients," said Arash Sabati, MD, FACC, pediatric cardiologist and non-invasive imaging specialist at Phoenix Children's. "The availability of agents like Optison will further enhance diagnostic imaging for pediatric patients, helping to ensure the best possible care."

Optison is currently indicated for use in patients with suboptimal echocardiograms. The FDA approved Optison for adults in 1997, and healthcare professionals have administered Optison to more than 5 million patients in the U.S.[1]. As the first of the second generation of UEAs to be approved by the FDA, the approval for the pediatric indication follows GE HealthCare's Phase IV, prospective open-label multicenter study to evaluate the efficacy of Optison for contrast-enhanced echocardiograms in patients. The study found that the use of intravenous Optison optimized endocardial border delineation, improved the visualization of left ventricular wall segments and reduced the number of suboptimal echocardiogram images in pediatric patients.

GE HealthCare's PDx segment is a global leader in imaging agents which supported over 130 million patient procedures in 2024, equivalent to four patient procedures every second. For more than 40 years, GE HealthCare imaging agents have been routinely used across MRI, X-ray/CT and ultrasound to enhance clinical images and support diagnosis.

About GE HealthCare Technologies Inc.

GE HealthCare is a trusted partner and leading global healthcare solutions provider, innovating medical technology, pharmaceutical diagnostics, and integrated, cloud-first AI-enabled solutions, services and data analytics. We aim to make hospitals and health systems more efficient, clinicians more effective, therapies more precise, and patients healthier and happier. Serving patients and providers for more than 125 years, GE HealthCare is advancing personalized, connected and compassionate care, while simplifying the patient's journey across care pathways. Together, our Imaging, Advanced Visualization Solutions, Patient Care Solutions and Pharmaceutical Diagnostics businesses help improve patient care from screening and diagnosis to therapy and monitoring. We are a $19.7 billion business with approximately 53,000 colleagues working to create a world where healthcare has no limits.

GE HealthCare is proud to be among 2025 Fortune World's Most Admired Companies™.

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Important Safety Information
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 echocardiograms 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 OPTISN 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 $\geq$ 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 patients 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

[1] Data on File – May 2, 2025

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