DEFINITY®
VIAL FOR (Perflutren Lipid Microsphere)
INJECTABLE SUSPENSION

- Impacts cardiac diagnosis[3]
- Avoids additional diagnostic procedures[3]
- Alters patient management decisions[3]
- Reduces resource utilization and per-patient expense[3]

INDICATIONS

Activated DEFINITY® (Perflutren Lipid Microsphere) Injectable Suspension is indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

DEFINITY® is indicated for use in patients in contrast-enhanced diagnostic ultrasound imaging to improve characterization of focal lesions of the liver and kidney.

CONTRAINDICATIONS

Activated DEFINITY® should not be administered to patients with known hypersensitivity to octafluoropropane or in patients with known cardiac shunts (see WARNINGS).

Activated DEFINITY® should not be administered by direct intra-arterial injection (see WARNINGS).

IMPORTANT SAFETY INFORMATION

Serious cardiopulmonary reactions, including fatalities, have occurred uncommonly during or following perflutren-containing microsphere administration (see WARNING). The risk for these reactions may be increased among patients with unstable cardiopulmonary conditions (see ADVERSE REACTION). In these patients, monitor vital signs, electrocardiography, and cutaneous oxygen saturation during and for at least 30 minutes after DEFINITY® administration. Always have cardiopulmonary resuscitation personnel and equipment readily available prior to DEFINITY® administration and monitor all patients for acute reactions.

Please see the full prescribing information for DEFENITY Vial for (Perflutren Lipid Microsphere) Injectable Suspension.

REFERENCES: 1. Becher H, Burns PN. Handbook of Contrast Echocardiography: Left Ventricular Function and Myocardial Perfusion. Heidelberg, NY: Springer-Verlag; 2000:2-44. **2.** Kitzman DW, et al. Efficacy and Safety of the Novel Ultrasound Contrast Agent Perflutren (DEFINITY) in Patients with Suboptimal Baseline Left Ventricular Echocardiographic Images. Am J Cardiol. 2000;86:669-674. **3.** Kurt M, et al. Impact on Contrast Echocardiography on Evaluation of Ventricular Function and Clinical Management in a Large Prospective Cohort. J. Am. Coll. Cardiol. 2009;53:802-810. **4.** DEFINITY® [package insert]. N. Billerica, MA: Lantheus Medical Imaging, Inc., 2017. **5.** http://www.lantheus.com/assets/lantheus_vialmix_manual.pdf. Accessed February 17, 2017. **6.** Sboros V, et al. Contrast Agent Stability: A Continuous B-Mode Imaging Approach. Ultrasound in Med. & Biology. 2001;27:1367-1377. **7.** Data on file, Lantheus Medical Imaging, Inc.

Imported & Distributed in India by:
J. B. CHEMICALS & PHARMACEUTICALS LIMITED
Cnergy IT Park, Unit A2, 3rd Floor, Unit A, 8th Floor, Appa Saheb Marathe Marg, Prabhadevi, Mumbai - 400 025. Phone: +91 22 2439 5200 / 2439 5500. Website: www.jbcpl.com

Lantheus Medical Imaging

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

DEFINITY® Dosing & Administration

A single vial is sufficient to capture essential diagnostic information[1-3]

DEFINITY® offers flexibility in dosing to meet patient and practice-specific needs[4]

DEFINITY®
VIAL FOR (Perflutren Lipid Microsphere)
INJECTABLE SUSPENSION

Activate DEFINITY® with VIALMIX®

- Once activated, DEFINITY® appears as a milky white suspension
- If activated vial is not used within 5 minutes, resuspend with 10 seconds of hand agitation

VIALMIX® delivers consistency in the preparation of DEFINITY®[4,5]

Unactivated DEFINITY®

Activated DEFINITY®

Mechanical agitation with VIALMIX® delivers consistent size and number of microbubbles contributing to predictable image quality from study to study[4,6]

DEFINITY® may be used for up to 12 hours after activation with VIALMIX®. If not used within 12 hours, vial may be returned to refrigeration and reactivated once with VIALMIX® within 24 hours. Reactivated DEFINITY® may be used for up to 12 hours.[4,7]

DEFINITY®
VIAL FOR (Perflutren Lipid Microsphere)
INJECTABLE SUSPENSION

It is important to vent the vial when withdrawing activated DEFINITY®
Venting avoids negative pressure in the vial; allows for easier withdrawal to prevent microbubble disruption

- Vent vial with an additional needle by placing needle tip in the activated DEFINITY® vial
- Attach 18 or 20 gauge needle to syringe; place needle in the vial
- Invert vial and withdraw the activated DEFINITY® from the middle of the liquid -

Do not inject air into the vial

Dosing & Administration

Diluted Bolus[4]*	Continuous Infusion[4]	Bolus[4]
Combine 1.3 mL activated DEFINITY® with 8.7 mL of preservative-free saline in a 10-cc syringe • Gently hand-agitate to evenly distribute microbubbles • Administer ~1 to 2 mL slowly with subsequent injections as needed ** Better suited for low MI nonlinear imaging*	Combine 1.3 mL activated DEFINITY® with 50 mL of preservative-free saline • Gently squeeze IV bag to evenly distribute microbubbles • Initiate at 4 mL/minute; maximum 10 mL/minute • Adjust flow rate for optimal image enhancement	Withdraw 10 µL/kg activated DEFINITY® • Administer slowly over 30 to 60 seconds • Follow with a 10 mL saline flush • Subsequent injection as needed Smaller, incremental dose amounts of 0.2 mL to 0.3 mL are better suited for current ultrasound system technology Maximum allowable dose is 20 µL/kg

DEFINITY®
VIAL FOR (Perflutren Lipid Microsphere)
INJECTABLE SUSPENSION