

IMPORTANT PRESCRIBING INFORMATION

6 May 2008

Dear Healthcare Provider:

Lantheus Medical Imaging is writing to inform you of important safety changes to the prescribing information for activated DEFINITY[®] (Perflutren Lipid Microsphere) Injectable Suspension. This Important Prescribing Information supersedes the previous Dear Healthcare Provider letter dated 10 October 2007 and addresses the product benefit/risk assessment based upon recent safety information provided to FDA.

DEFINITY[®] is an ultrasound contrast agent intended to be used in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border.

These changes include revisions to the boxed WARNING, WARNINGS and CONTRAINDICATIONS sections of the prescribing information.

Boxed WARNING

The second bullet within the boxed warning has been revised to describe monitoring in patients with pulmonary hypertension or unstable cardiopulmonary conditions.

WARNING: Serious Cardiopulmonary Reactions

Serious cardiopulmonary reactions, including fatalities, have occurred during or following perflutren-containing microsphere administration.

- **Assess all patients for the presence of any condition that precludes DEFINITY[®] administration (see CONTRAINDICATIONS).**
- **In patients with pulmonary hypertension or unstable cardiopulmonary conditions, monitor vital signs, electrocardiography and cutaneous oxygen saturation during and for at least 30 minutes after DEFINITY[®] administration (see WARNINGS).**
- **Always have resuscitation equipment and trained personnel readily available.**

Revised CONTRAINDICATIONS

Contraindications have been revised to the following:

Do not administer DEFINITY[®] to patients with known or suspected

- Right-to-left, bi-directional, or transient right-to-left cardiac shunts,
- Hypersensitivity to perflutren (see Warnings)

Do not administer DEFINITY[®] by intra-arterial injection.

All other contraindications have been removed.

Revised WARNINGS

The Warning section has been revised to reflect monitoring in patients with pulmonary hypertension or unstable cardiopulmonary conditions.

Serious Cardiopulmonary Reactions

Serious cardiopulmonary reactions, including fatalities, have occurred during or following perflutren-containing microsphere administration. The risk for these reactions may be increased among patients with pulmonary hypertension or unstable cardiopulmonary conditions (acute myocardial infarction, acute coronary artery syndromes, worsening or unstable congestive heart failure, serious ventricular arrhythmias or respiratory failure, including patients receiving mechanical ventilation). In these patients, monitor vital signs, electrocardiography, and cutaneous oxygen saturation during and for at least 30 minutes after DEFINITY[®] administration. In the absence of these underlying conditions, observe patients closely during and following DEFINITY[®] administration.

In postmarketing use, uncommon but serious reactions observed during or shortly following perflutren-containing microsphere administration included fatal cardiac or respiratory arrest, loss of consciousness, convulsions, symptomatic arrhythmias (atrial fibrillation, supraventricular tachycardia, ventricular tachycardia or fibrillation), hypotension, respiratory distress or cardiac ischemia (see ADVERSE REACTIONS).

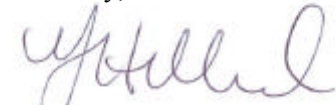
Always have cardiopulmonary resuscitation personnel and equipment readily available prior to DEFINITY[®] administration and monitor all patients for acute reactions.

Lantheus Medical Imaging remains committed to providing you the most current and accurate information available for our products.

For any questions about DEFINITY[®] or to report adverse events suspected to be associated with the use of DEFINITY[®], please call Lantheus Medical Imaging's Medical Information Department at **1-800-343-7851** from 9.00am to 5.00pm EST, Monday to Friday.

Alternatively, adverse event information may be reported to FDA's MedWatch Reporting System by phone at **1-800-FDA-1088**, by facsimile at 1-800-FDA-0178, or by mail using Form 3500 at <http://www.fda.gov/medwatch/index.html>.

Sincerely,



Mark Hibberd, M.D.
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