



















OPTISON™

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

Since 1997, over 3 million doses shipped worldwide¹

<p>December 1997</p>  <p>Approved by the FDA for ultrasound enhancing imaging in the US</p>	<p>January 1998</p>  <p>Launched as the first second-generation ultrasound enhancing agent for the US market</p>	<p>May 1998</p>  <p>Launched in the European market</p>	<p>December 2002</p>  <p>Transfer of Optison from Mallinckrodt Pharmaceuticals to Amersham Health</p>	<p>April 2004</p>  <p>GE Healthcare acquires Amersham Health</p>	<p>November 2005</p>  <p>GE Healthcare voluntarily recalled Optison due to manufacturing issues at Mallinckrodt</p>	<p>November 2007</p>  <p>Optison relaunched for US echocardiography market</p>	<p>May 2008</p>  <p>FDA revises Boxed Warning for ultrasound enhancing agents</p>
<p>August 2012</p>  <p>Positive updates to Optison label approved by the FDA</p>	<p>December 2013</p>  <p>1.5 million doses shipped worldwide in 15 years</p>	<p>January 2014</p>  <p>GE Healthcare moves manufacturing to company's Oslo site</p>	<p>April 2016</p>  <p>New 18-vial carton</p>	<p>September 2016</p>  <p>FDA removes cardiac shunt contraindication</p>	<p>March 2021</p>  <p>FDA approves storage at room temperature up to 24 hours</p>	<p>July 2021</p>  <p>Optison no longer requires temperature controlled shipping, though should be refrigerated upon receipt</p>	<p>September 2021</p>  <p>FDA removes blood and blood products hypersensitivity contraindication, further confirming Optison is not a blood product</p>

IMPORTANT SAFETY INFORMATION ABOUT OPTISON

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

• **CONTRAINDICATION:** Do not administer OPTISON to patients with known or suspected hypersensitivity to perflutren or albumin.

Please see Full Prescribing Information [here](#) for additional Important Safety Information About Optison.

Reference: 1. Data on file. GE Healthcare; 2021.

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