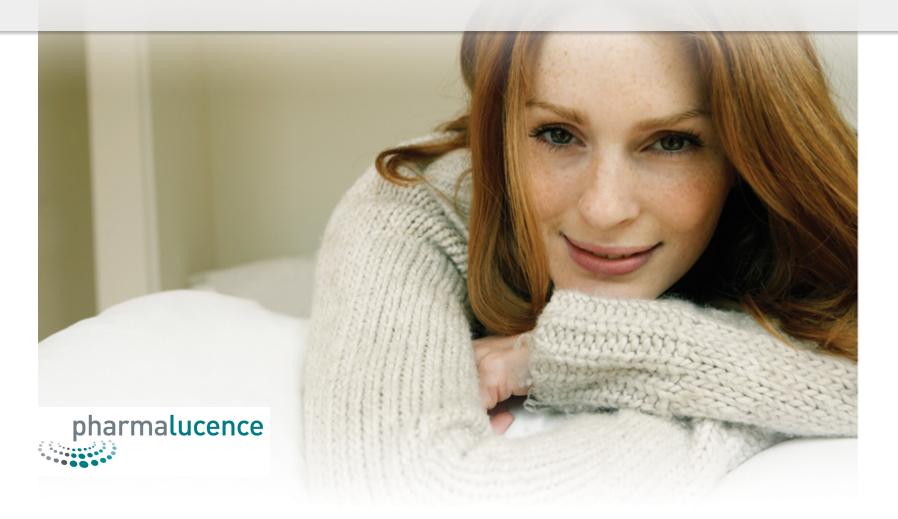
Sulfur Colloid Injection

For Subcutaneous, Intraperitoneal, Intravenous and Oral Use For Diagnostic Use by Prescription Only



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Indications

- In adults, indicated to assist in the localization of lymph nodes draining a primary tumor in patients with breast cancer or malignant melanoma when used with a hand-held gamma counter.
- In adults, to assist in the evaluation of peritoneo-venous (LeVeen) shunt patency.
- Indicated for imaging areas of functioning reticuloendothelial cells in the liver, spleen and bone marrow.
- Indicated for studies of esophageal transit and gastroesophageal reflux, and detection of pulmonary aspiration of gastric contents
- Indicated for subcutaneous, intraperitoneal, intravenous and oral administration.

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Fair balance

- Warnings and Precautions Anaphylactic reactions including rare fatalities have occurred following intravenously administered Technetium Tc 99m Sulfur Colloid. Have resuscitation equipment and personnel immediately available.
- Adverse Reactions The most frequently reported adverse reactions include rash, urticaria, anaphylactic shock, and hypotension.
- To view complete prescribing information, visit www.pharmalucence.com



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Sulfur Colloid - Proven

In Lymph Node Localization studies for breast cancer using Sulfur Colloid and blue dye, SCI effectively localized in one lymph node in **94%** of all studies performed, while blue dye was shown to localize in only 85%⁽¹⁾

In Lymph Node Localization studies for melanoma using Sulfur Colloid and blue dye, SCI effectively localized in one lymph node in **96%** of all studies performed, while blue dye was shown to localize in only 84%⁽²⁾

⁽¹⁾ In 9,213 procedures using both Sulfur Colloid and blue dye, as cited in FDA approved product labeling for Sulfur Colloid (July 2011).

⁽²⁾ In 249 patients using both Sulfur Colloid and blue dye, as cited in FDA approved product labeling for Sulfur Colloid (August 2012).



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Sulfur Colloid - Trusted

Professional Societies recognize that Lymph Node Localization (LNL) studies performed with Sulfur Colloid Injection (SCI) are the established **standard of care** in breast cancer and melanoma patient management (3,4,5)

- ASCO (American Society of Clinical Oncology) guidelines for Breast Cancer and Melanoma
- Joint Clinical Practice Guideline, ASCO and SCO (Society of Surgical Oncology) for Melanoma
- SNM (Society of Nuclear Medicine) guidelines for Melanoma
- EANM and SNMMI guidelines for breast cancer⁽⁶⁾

⁽³⁾ Sentinel Lymph Node Biopsy in Early-Stage Breast Cancer, American Society of Clinical Oncology Clinical Practice Guideline Update, Vol 32, No 13 (May 1), 2014: pp. 1365-1383.

⁽⁴⁾ Sentinel Lymph Node Biopsy for Melanoma: American Society of Clinical Oncology and Society of Surgical Oncology Joint Clinical Practice Guideline, August 2012.

⁽⁵⁾ Society of Nuclear Medicine Procedure Guideline for Lymphoscintigraphy and the Use of Intraoperative Gamma Probe for Sentinel Lymph Node Localization in Melanoma of Intermediate Thickness, June 2002.

⁽⁶⁾ The EANM and SNMMI practice guideline for lymphoscintigraphy and sentinel node localization in breast cancer, August 2013.



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Sulfur Colloid - Safe

In 8730 patients studied in 13 clinical publications evaluated for patient safety in lymph node localization in either breast cancer or melanoma patients, there were **no adverse events** reported attributed to Sulfur Colloid⁽⁷⁾

(7) Pharmalucence Sulfur Colloid s-NDA submissions to FDA (Approved 2011 and 2012).



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Outcomes Study - Demonstrated Effectiveness

Krag DN, Anderson SJ, Julian TB, Brown AM, Harlow SP, Ashikaga T, et al.

"Technical outcomes of sentinel-lymph-node resection and conventional axillary-lymph-node dissection in patients with clinically node-negative breast cancer: Results from the NSABP B-32 randomized Phase III trials."

Lancet Oncology (2007); 8(10) 881-888 (1)

- 5536 patients studied using Sulfur Colloid
- Excerpt from the Summary:

"the B-32 trial is the only trial of sufficient size to provide definitive information related to the primary outcome measures of survival and regional control."

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Sulfur Colloid - Summary

- Widely available
- Economically priced
- Well established
- Recognized standard of care
- Decades of use across several indications with proven safety and efficacy profile
- Efficacy in LNL studies supported by vast compendium of literature

For more information www.sulfurcolloid.com