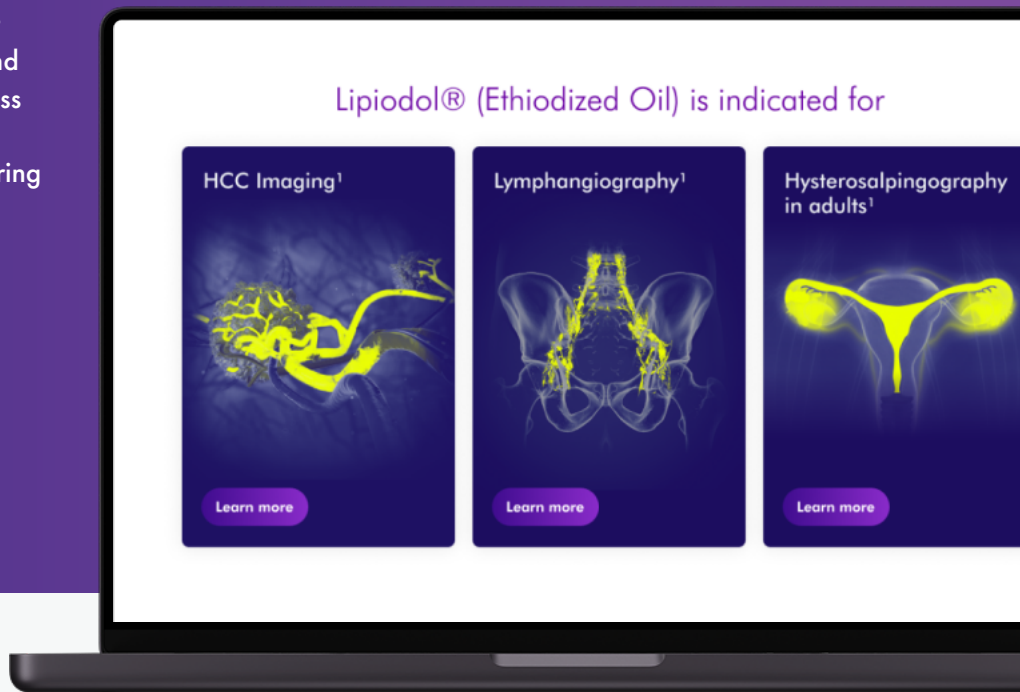


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[www.lipiodol.com](http://www.lipiodol.com)



## Start Exploring

A powerful resource for Lipiodol product information, expert education, and customer support.



### Expert connections

Collaborate with experts eager to share their knowledge across various clinical focus areas through workshops, courses, and consultations. These experts will support their peers and help advance clinical practice.



### Education opportunities

Take advantage of educational opportunities including a clinical support network, our symposium and speaker series, continuing education programs, and immersive VR experiences.



### Product information

Discover information about Lipiodol, the first and only iodinated oil-based contrast agent in the U.S., including indications for use and how Lipiodol works. The site offers concise but detailed information to support confident decision-making.



### Events and resources

Stay informed about upcoming events where you can connect with our team. Access valuable resources, from clinical data and expert insights to tools that support your practice.

# Lipiodol® (Ethiodized oil) injection

## Important Safety Information

### **WARNING: FOR INTRALYMPHATIC, INTRAUTERINE AND SELECTIVE HEPATIC INTRA-ARTERIAL USE ONLY**

See Full Prescribing Information for complete Boxed Warning.

Pulmonary and cerebral embolism can result from inadvertent intravascular injection or intravasation of Lipiodol.

Inject Lipiodol slowly with radiologic monitoring; do not exceed recommended dose.

### **INDICATION AND USAGE**

LIPIODOL® (ethiodized oil) injection is a prescription oil-based radio-opaque contrast agent indicated for:

- hysterosalpingography in adults
- lymphography in adult and pediatric patients
- selective hepatic intra-arterial use for imaging tumors in adults with known hepatocellular carcinoma (HCC)

### **CONTRAINDICATIONS**

LIPIODOL® is contraindicated in patients with hypersensitivity to LIPIODOL®, hyperthyroidism, traumatic injuries, recent hemorrhage or bleeding.

- LIPIODOL® Hysterosalpingography is contraindicated in pregnancy, acute pelvic inflammatory disease, marked cervical erosion, endocervicitis and intrauterine bleeding, in the immediate pre- or postmenstrual phase, and within 30 days of curettage or conization or patients with known or suspected reproductive tract neoplasia due to the risk of peritoneal spread of neoplasm.
- LIPIODOL® Lymphography is contraindicated in patients with a right to left cardiac shunt, advanced pulmonary disease, tissue trauma or hemorrhage, advanced neoplastic disease with expected lymphatic obstruction, previous surgery interrupting the lymphatic system, radiation therapy to the examined area.
- LIPIODOL® Selective Hepatic Intra-arterial Injection is contraindicated in the presence of dilated bile ducts unless external biliary drainage was performed before injection.

### **WARNINGS AND PRECAUTIONS**

- Pulmonary and cerebral embolism may occur immediately or after a few hours to days from inadvertent systemic vascular injection or intravasation of LIPIODOL®. Avoid use in patients with severely impaired lung function, cardiorespiratory failure or right-sided cardiac overload.
- Anaphylactoid and anaphylactic reactions with cardiovascular, respiratory or cutaneous manifestations, ranging from mild to severe, including death, have uncommonly occurred following LIPIODOL® administration. Avoid use in patients with a history of sensitivity to other iodinated contrast agents, bronchial asthma or allergic disorders because of an increased risk of a hypersensitivity reaction to LIPIODOL®.
- LIPIODOL® hepatic intra-arterial administration can exacerbate chronic liver disease.
- Iodinated contrast media can affect thyroid function because of the iodide content and can cause hyperthyroidism or hypothyroidism.

### **ADVERSE REACTIONS**

- Hysterosalpingography – Abdominal pain, foreign body reactions, exacerbation of pelvic inflammatory disease, salpingitis or pelvic peritonitis have been reported after the examination in case of latent infection.
- Lymphography – Lymphangitis, thrombophlebitis, edema or exacerbation of preexisting lymphedema, dyspnea and cough, iodism, allergic dermatitis, lipogranuloma, delayed healing at the site of incision.
- Selective Hepatic Intra-arterial Injection – Abdominal pain, nausea, and vomiting are the most common reactions; other reactions include hepatic vein thrombosis, hepatic ischemia, liver enzymes abnormalities, transitory decrease in liver function, liver decompensation and renal insufficiency. Procedural risks include vascular complications and infections.

### **USE IN SPECIFIC POPULATIONS**

- **Pregnancy:** The use of LIPIODOL® before or during pregnancy may interfere with thyroid function in both the pregnant woman and her fetus and may affect fetal development. Untreated hypothyroidism in pregnancy is associated with adverse perinatal outcomes, such as spontaneous abortion, preeclampsia, preterm birth, abruptio placentae, and fetal death. The use of LIPIODOL® before or during pregnancy causes iodide transfer across the placenta which may interfere with fetal thyroid function and may affect fetal development. Untreated hypothyroidism is also associated with increased fetal risk of low birth weight, fetal distress, and impaired neuropsychological development. Consider thyroid function testing during pregnancy if a woman was exposed to LIPIODOL® either before or during pregnancy, and also in infants whose mothers were exposed to LIPIODOL® before and during pregnancy or if clinically indicated.
- **Pregnancy Testing:** Confirm that the patient has a negative pregnancy test within 24 hours before LIPIODOL® administration for hysterosalpingography.
- **Lactation:** The use of LIPIODOL® may increase the concentration of iodide in human milk and may interfere with the thyroid function of the breastfed infant. Consider thyroid function testing in a breastfed infant whose mother was exposed to LIPIODOL® or if clinically indicated.
- **Pediatric:** For lymphography use a dose of minimum of 1 mL to a maximum of 6 mL according to the anatomical area to be visualized. Do not exceed 0.25 mL/kg. Administer the smallest possible amount of LIPIODOL® according to the anatomical area to be visualized.
- **Geriatric:** There are no studies conducted in geriatric patients.
- **Renal Impairment:** Prior to an intra-arterial administration of LIPIODOL® screen all patients for renal dysfunction by obtaining history and/or laboratory tests. Consider follow-up renal function assessments for patients with a history of renal dysfunction.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Lipiodol® is a registered trademark of Guerbet and is available by prescription only.

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