Lipiodol is an oil-based radio-opaque contrast agent indicated for:

**INDICATIONS AND USE**

Use a glass syringe to draw and inject Lipiodol.

**DOSE AND ADMINISTRATION**

**3 DOSE FORMS AND STRENGTHS**

**CONTRAINDICATIONS**

- Hypersensitivity to Lipiodol, hyperthyroidism, traumatic injuries, recent hemorrhage or bleeding.
- Pregnancy
- Nursing Mothers
- Pediatric Use
- Drug Interactions
- Adverse Reactions
- Use in Specific Populations
- Precautions
- Overdosage
- Clinical Pharmacology
- Nonclinical Toxicology
- How Supplied/Storage and Handling

Pediatric patients:
- Inject a 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.
- Selective Hepatic Intra-arterial Use
- Inject 1.5 to 15 mL of Lipiodol slowly under continuous radiologic monitoring. Do not exceed 20 mL total dosage.

**FULL PRESCRIBING INFORMATION: CONTENTS**

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
6 ADVERSE REACTIONS
7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS
9 PRECAUTIONS
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
13 NONCLINICAL TOXICOLOGY
16 HOW SUPPLIED/STORAGE AND HANDLING

*Sections or subsections omitted from the full prescribing information are not listed.

Pediatric patients:
- Inject a 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.
- Selective Hepatic Intra-arterial Use
- Inject 1.5 to 15 mL of Lipiodol slowly under continuous radiologic monitoring. Do not exceed 20 mL total dosage.

**DOSE FORMS AND STRENGTHS**

Each mL of Lipiodol contains 480 mg iodine organically combined with ethyl esters of fatty acids of poppy seed oil.

**CONTRAINDICATIONS**

- Hypersensitivity to Lipiodol, hyperthyroidism, traumatic injuries, recent hemorrhage or bleeding.
- Pregnancy
- Nursing Mothers
- Pediatric Use
- Drug Interactions
- Adverse Reactions
- Use in Specific Populations
- Precautions
- Overdosage
- Clinical Pharmacology
- Nonclinical Toxicology
- How Supplied/Storage and Handling

Pediatric patients:
- Inject a 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.
- Selective Hepatic Intra-arterial Use
- Inject 1.5 to 15 mL of Lipiodol slowly under continuous radiologic monitoring. Do not exceed 20 mL total dosage.

**DOSE FORMS AND STRENGTHS**

Each milliliter of Lipiodol contains 480 mg iodine organically combined with ethyl esters of fatty acids of poppy seed oil.
4 CONTRAINDICATIONS
Lipiodol is contraindicated in patients with hypersensitivity to Lipiodol, hypothyroidism, traumatic injuries, recent hemorrhage or bleeding.

Hysterosalpingography
Lipiodol hysterosalpingography is contraindicated in pregnancy, acute pelvic inflammatory disease, marked cervical erosion, endocervicitis and intrauterine bleeding, in the immediate pre- or postmenstrual phase, or within 30 days of curettage or conization.

Lymphography
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.

Selective Hepatic Intra-arterial Use Patients with HCC
Lipiodol use is contraindicated in areas of the liver where the bile ducts are dilated unless external biliary drainage was performed before injection.

5 WARNINGS AND PRECAUTIONS
5.1 Pulmonary and Cerebral Embolism
Pulmonary embolism may occur immediately or after a few hours to days from inadvertent systemic vascular injection or intravasation of Lipiodol and cause decreased pulmonary diffusing capacity and pulmonary blood flow, pulmonary infarction, acute respiratory distress syndrome and fatalities. Embolization of Lipiodol to brain and other major organs may occur. Avoid use of Lipiodol in patients with severely impaired lung function, cardiopulmonary failure, or right-sided cardiac overload. Perform radiological monitoring during the Lipiodol injection. Do not exceed the recommended maximum dose and rate of injection of Lipiodol. During lymphography to minimize the risk of pulmonary embolism obtain radiographic confirmation of intralymphatic (rather than venous) injection, and terminate the procedure when Lipiodol becomes visible in the thoracic duct or lymphatic obstruction is observed.

5.2 Hypersensitivity Reactions
Anaphylactic and anaphylactoid 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. Administer Lipiodol only in situations where trained personnel and therapies are promptly available for the treatment of hypersensitivity reactions, including personnel trained in resuscitation; ensure continuous medical monitoring and maintain an intravenous access line. Most hypersensitivity reactions to Lipiodol occur within half an hour after administration. Delayed reactions can occur up to several days after administration. Observe patients for signs and symptoms of hypersensitivity reactions during and for at least 30 minutes following Lipiodol administration.

5.3 Exacerbation of Chronic Liver Disease
Lipiodol hepatic intra-arterial administration can exacerbate the following conditions: portal hypertension and cause variceal bleeds due to obstruction of the intrahepatic portal channels by opening a pre sinusoidal anastomosis; hepatic ischemia and cause liver enzyme elevations, fever and abdominal pain; hepatic failure and cause ascites and encephalopathy. Hepatic vein thrombosis, irreversible liver insufficiency and fatalities have been reported. Procedural risks include vascular complications and infections.

5.4 Thyroid Dysfunction
Iodinated contrast media can affect thyroid function because of the free iodine content and can cause hyperthyroidism or hypothyroidism in predisposed patients. Patients at risk are those with latent hyperthyroidism and those with Hashimoto thyroiditis, or history of thyroid irradiation. As Lipiodol may remain in the body for several months, thyroid diagnostic results can be affected for up to two years after lymphography.

6 ADVERSE REACTIONS
6.2 Postmarketing Experience
The following adverse reactions (Table 1) have been identified during post approval use of Lipiodol. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions are described in more detail in other sections of the prescribing information:

Pulmonary and cerebral embolism [see Warnings and Precautions (5.1)]
Hypersensitivity reactions [see Warnings and Precautions (5.2)]
Exacerbation of chronic liver disease [see Warnings and Precautions (5.3)]

Table 1: Adverse Reactions in the Postmarketing Experience

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>Adverse Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endocrine disorders</td>
<td>hypothyroidism, hyperthyroidism, thyrotoxicosis</td>
</tr>
<tr>
<td>Eye disorders</td>
<td>retinal vein thrombosis</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>nausea, vomiting, diarrhea</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>fever, pain, granuloma</td>
</tr>
<tr>
<td>Hepatobiliary disorders</td>
<td>hepatic vein thrombosis</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td>hypersensitivity, anaphylactic reaction, anaphylactoid reaction</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>General edema</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>pulmonary embolism, dyspnea, cough, acute respiratory distress syndrome</td>
</tr>
<tr>
<td>Urinary system disorders</td>
<td>renal insufficiency</td>
</tr>
</tbody>
</table>

Hysterosalpingography
Abdominal pain, foreign body reactions, exacerbation of pelvic inflammatory disease.

Lymphography
Cardiovascular collapse, lymphangitis, thrombophlebitis, edema or edema of pre-existing lymphedema, dyspnea and cough, fever, iodine, headache, soreness of mouth and pharynx, coryza and skin rash), allergic dermatitis, lipogranuloma, delayed healing at the site of incision.

Selective Hepatic Intra-arterial Injection
Fever, abdominal pain, nausea, and vomiting are the most common reactions; other reactions include hepatic ischemia, liver enzymes abnormalities, transitory decrease in liver function, liver decompensation and renal insufficiency. Procedural risks include vascular complications and infections.