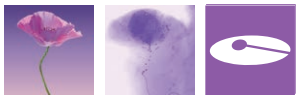
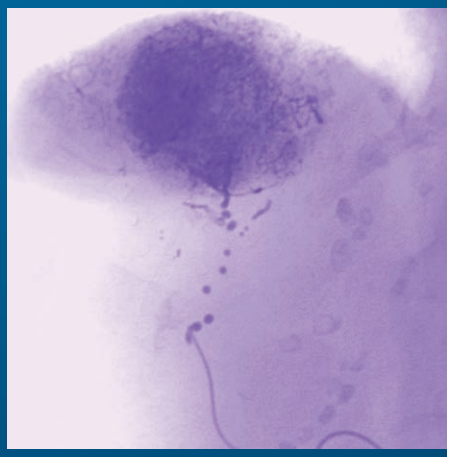


LIPIODOL® ULTRA FLUID

Ethyl esters of iodized fatty acids of poppy seed oil

Contrast agent for interventional radiology



Guerbet

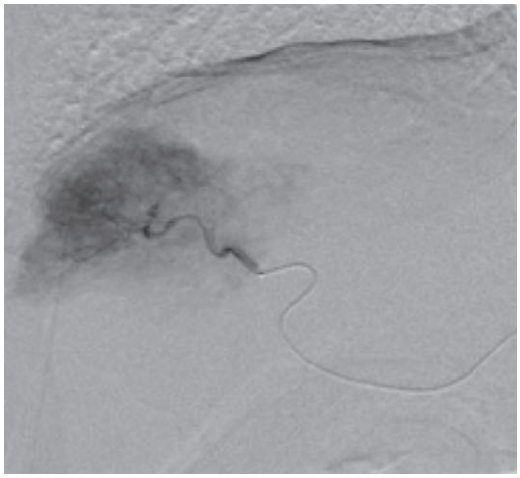
Contrast for Life

Main indications

- **Liver lesion diagnosis**
- **Vascular embolization with surgical glue**
- **Hysterosalpingography**
- **Lymphography**

Liver lesion diagnosis

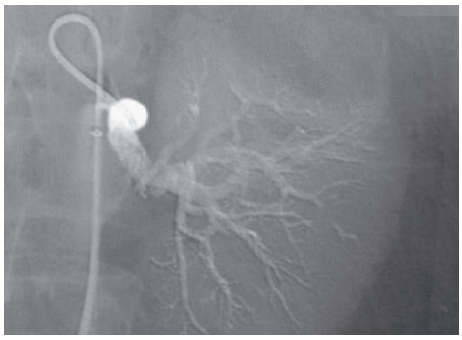
The standard dose depends on lesion size and can vary from 2 to 10 mL per patient. **LIPIODOL® ULTRA FLUID** is sometimes mixed with small amounts of water-soluble iodinated contrast agents. The CT scan should be performed 7 to 15 days after the selective injection to allow the **LIPIODOL® ULTRA FLUID** to be eliminated from the non-tumoral liver tissue.



- **Selective angiography of the anterior-superior subsegmental branch of the right hepatic artery, showing hypervascular tumor adjacent to the diaphragm. Transarterial chemoembolization was performed: mixture of iodized oil (LIPIODOL®) and epirubicin hydrochloride (30-50 mg)**
  Manabu Morimoto / European Journal of Radiology 82 (2013) 497-503

Vascular embolization

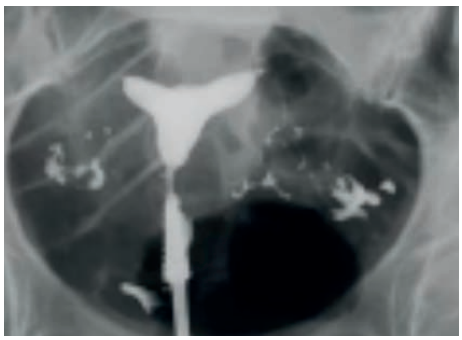
The dose of **LIPIODOL® ULTRA FLUID** administered at each embolization session depends on lesion size. The **LIPIODOL®** and liquid embolizing agent mixture may vary from 20 to 80% but usually consists of a 50/50 mixture. The volume injected should not exceed 15 mL.



■ Control after embolization with radio-opaque mixture of cyanoacrylate and LIPIODOL® ULTRA FLUID: obstruction of the vascular territory with preservation of the ostium permeability of the renal artery to facilitate the surgery
Courtesy of Dr. Loffroy R. Dijon France

Hysterosalpingography

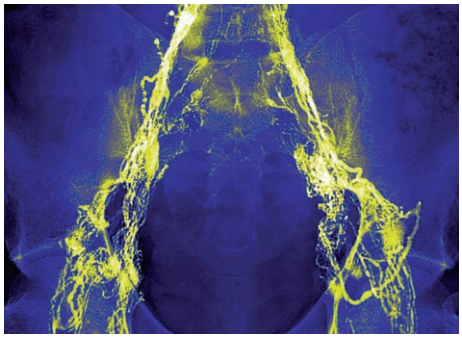
Average dose: quantity must be adjusted according to uterine volume. Total volume: 5 to 20 mL.



■ Hysterosalpingography with LIPIODOL® ULTRA FLUID
Courtesy of Dr. Niel Johnson, University of Auckland, New Zealand

Lymphography

5 to 7 mL by intra-lymphatic injection only for opacification of a limb (the dose being adapted to the height of the patient), i.e. 10 mL to 14 mL for bilateral pedal lymphography.



■ Conventional abdominal view of lymphatic vessels and lymph nodes (colorized image)
Courtesy of Dr. Ali Guermazi, Hospital Saint Louis, Paris, France

Physical Characteristics

Ethyl esters of iodized fatty acids of poppy seed oil

Iodine content	Density at 15°C	Viscosity at 37°C
480 mg/ml	1.280g/cm²	25 mPa.s

Indication per country

	Hysterosalpingography	Lymphography	Urethrography	Nasal sinuses	Sialography	Fistulography	Diagnostic of liver lesion	Interv. Radiol. Glue	Interv. Radiol. Chimio	Cholangiography
Argentina		X					X	X		
Australia	X	X	X	X	X					
Austria		X							X	
Belgium		X								
Brazil		X					X	X		
Burkina Faso		X					X	X		
Canada	X	X			X	X				
Chile		X					X	X		
China		X								
Colombia		X					X	X		
Czech Rep.		X				X			X	
Denmark	X	X								
Egypt		X					X	X		
France		X					X	X	X	
Germany		X								
Hong Kong		X								
Hungary		X							X	
India		X					X	X		
Indonesia		X								
Iraq		X					X	X		
Ireland	X	X		X	X					
Israel		X								
Japan	X	X							X	
Luxemburg		X								
Malaysia		X								
Mexico	X	X	X	X	X	X	X	X		X
Morocco		X					X	X		
The Netherlands	X	X								
New Zealand	X	X								
Peru		X					X	X	X	
Philippines		X		X						
Portugal		X								
Russian Feder.		X								
Singapore		X								
South Africa		X		X		X				
South Korea		X			X				X	
Switzerland		X								
Taiwan	X	X	X		X	X				X
Thailand		X								
Tunisia		X					X	X		
Turkey		X							X	
U.K.	X	X		X	X					
U.S.A.	X	X					X			
Uruguay		X					X	X		
Venezuela		X					X	X		
Vietnam		X					X	X		

LIPIODOL® ULTRA-FLUID. Composition: Ethyl esters of iodized fatty acids of poppy seed oil 10 mL, corresponding to an iodine content of 480 mg/mL. **Indications(**):** In diagnostic radiology - Hysterosalpingography - Ascending urethrography – Lymphography – Sialography - Fistulography and exploration of abscesses - Exploration of frontal sinuses - Pre and post-operative cholangiography. In interventional radiology – Visualisation and localization (by selective intra-arterial use during CT) of liver lesions in adults with known or suspected hepatocellular carcinoma - Visualisation, localisation and vectorisation during Trans-Arterial Chemo-Embolisation (TACE) of hepatocellular carcinoma at intermediate stage, in adults – Selective embolization in combination with Histoacryl glue (particularly for arteriovenous malformation or aneurysms) – Selective injections of LIPIODOL ULTRA-FLUID into the hepatic artery for diagnostic purposes where a spiral CT scan is not practical. In endocrinology - Prevention of severe cases of iodine deficiency. **Posology and method of administration (*):** have to be adapted according to the type of examination, the territories explored, the age and weight of the patient. The volume to be administered depends on the particular requirements of the technique and the size of the patient. **Contraindications:** Hypersensitivity to LIPIODOL ULTRA-FLUID - Confirmed hyperthyroidism - Patients with traumatic injuries, recent haemorrage or bleeding – Hysterosalpingography during pregnancy or acute pelvic inflammation – Bronchography. In interventional radiology (Trans-Arterial Chemo-Embolization), Administration in liver areas with dilated bile ducts unless drainage has been performed. **Special warnings and special precautions for use(*):**There is a risk of hypersensitivity regardless of the dose administered. Lymphography: Pulmonary embolism may occur immediately or after few hours to days from inadvertent systemic vascular injection or intravasation of LIPIODOL ULTRA-FLUID: Perform radiological monitoring during LIPIODOL ULTRA-FLUID injection and avoid use in patients with severely impaired lung function, cardiorespiratory failure or right-sided cardiac overload. Hypersensitivity: all iodinated contrast agents can lead to minor or major hypersensitivity reactions, which can be life-threatening. These hypersensitivity reactions are of an allergic nature (known as anaphylactic reactions if they are serious) or a non-allergic nature. They can be immediate (occurring within 60 min) or delayed (not occurring until up to 7 days later). Anaphylactic reactions are immediate and can be fatal. They are dose-independent, can occur right from the first administration of the product, and are often unpredictable: 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 ULTRA-FLUID. Thyroid: can cause hyperthyroidism in predisposed patients. Lymphography saturates the thyroid with iodine for several months and thyroid exploration should be performed before radiological examination. Chemo-Embolization: Trans-Arterial Chemo-Embolisation is not recommended in patients with decompensated liver cirrhosis (Child-Pugh ≥8), advanced liver dysfunction, macroscopic invasion and/or extra-hepatic spread of the tumour. Renal insufficiency must be prevented by correct rehydration before and after the procedure. Oesophageal varices must be carefully monitored. Hepatic intra-arterial treatment can progressively cause an irreversible liver insufficiency in patients with serious liver malfunction and/or undergoing close multiple sessions. The risk of superinfection in the treated area is normally prevented by administration of antibiotics. Embolization with glue: An early polymerisation reaction may exceptionally occur between LIPIODOL ULTRA-FLUID and certain surgical glues, or even certain batches of glue. Before using new batches of LIPIODOL ULTRA-FLUID or surgical glue, the compatibility of LIPIODOL ULTRA-FLUID and the glue must be tested in vitro. **Interaction with other medicinal products and other forms of interaction (*):** Metformin, Beta blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin-receptor antagonists, Diuretics, Interleukin II. **Fertility, pregnancy and lactation (*) :** LIPIODOL ULTRA-FLUID must only be used in pregnant women if absolutely necessary and under strict medical supervision. Breastfeeding should be discontinued if LIPIODOL ULTRA-FLUID must be used - **Effects on ability to drive and use machines:** The effects on ability to drive and to use machines have not been investigated - **Undesirable effects(*)** most adverse effects are dose-related and dosage should therefore be kept as low as possible :hypersensitivity, anaphylactic reaction, anaphylactoid reaction, vomiting, diarrhea, nausea, fever, pain, dyspnea, cough, hypothyroidism, hyperthyroidism, thyroiditis, pulmonary embolism, cerebral embolism, retinal vein thrombosis, lymphoedema aggravation, hepatic vein thrombosis, granuloma. **Overdose (*)** The total dose of LIPIODOL ULTRA-FLUID administered must not exceed 20 mL - **Pharmacodynamic properties (*)** Pharmacotherapeutic group: X-ray contrast media, iodinated; ATC code: V08A D01.Water-insoluble iodinated contrast medium. **Presentation (**)** - 10 mL glass ampoule, box of 1 - 10 mL glass ampoule, box of 50. **Marketing authorization holder (*):** Guerbet - BP 57400 - F-95943 Roissy CdG cedex – FRANCE. Information: tel : 33 (0) 1 45 91 50 00. Revision: September 2, 2015.

(*) For complete information please refer to the local Summary of Product Characteristics – (**) Indications, volumes and presentations may differ from country to country.

Reporting of suspected adverse reactions is important as it helps to continuously assess the benefit-risk balance. Therefore, Guerbet encourages you to report any adverse reactions to your health authorities or to our local Guerbet representative.

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P15 010 LUF – August 2015 – Creation: DDB® HealthParis – Realisation: CM communication