

June 3, 2016

Dear Healthcare Professional,

Due to recent manufacturing issues we would like to inform you of a critical shortage of **LIPIODOL® (ETHIODIZED OIL) INJECTION**. Guerbet is coordinating with the FDA to increase the availability of **LIPIODOL® (ETHIODIZED OIL) INJECTION** for US patients.

During this interim period, Guerbet is initiating a temporary importation of **LIPIODOL® ULTRA-FLUIDE**, ethyl esters of iodized fatty acids of poppy seed oil, lot #15LU606 to the United States market. **LIPIODOL® ULTRA-FLUIDE** contains the same drug components as **LIPIODOL® (ETHIODIZED OIL) INJECTION** (manufactured by Jubliant HollisterStier, Canada). **LIPIODOL® ULTRA-FLUIDE** is manufactured in compliance with European Good Manufacturing Practice (GMP) regulations by Delpharm Tours (France) for Guerbet. Delpharm Tours's manufacturing facility is FDA inspected. The FDA has not approved this product in the United States.

At this time, no other entity except Guerbet is authorized by the FDA to import or distribute **LIPIODOL® ULTRA-FLUIDE**.

Effective immediately, Guerbet will offer the following version:

<b>LIPIODOL® ULTRA-FLUIDE</b>	
<b>48% Iodine w/vol (i.e 480 mg Iodine/mL)</b> (ethyl esters of iodized fatty acids of poppy seed oil)	
10mL glass ampoule	Authorization #3400930621608 Box of 1 ampoule

*LIPIODOL® ULTRA-FLUIDE formulation is the same as LIPIODOL (Ethiodized Oil) Injection®.*

**The active substance of LIPIODOL® ULTRA-FLUIDE and LIPIODOL (ETHIODIZED OIL) INJECTION is the same (ethyl esters of iodized fatty acids of poppy seed oil, stabilized with 1% of poppy seed oil).**

The barcode used on **LIPIODOL® ULTRA-FLUIDE** is an international pharmaceutical manufacturing code and will likely not be recognized by scanning systems used in the United States. Institutions should confirm that barcode systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

For questions regarding **LIPIODOL® ULTRA-FLUIDE** in the United States, please contact Guerbet LLC at 1-877-729-6679 between the hours of 8 a.m. and 5 p.m. (ET), or email at [info-us@guerbet-group.com](mailto:info-us@guerbet-group.com).

Please click here for prescribing information: [LIPIODOL® ULTRA-FLUIDE Prescribing Information](#) and [LIPIODOL® \(ETHIODIZED OIL\) INJECTION Prescribing Information](#).

**Guerbet LLC**

One City Centre  
120 W. 7th St. • Suite 108  
Bloomington, IN 47404  
Tel: 812-333-0059  
Fax: 812-333-0084  
[www.guerbet-us.com](http://www.guerbet-us.com)



The product comparison table below also highlights the differences between **LIPIODOL<sup>®</sup> ULTRA-FLUIDE** and **LIPIODOL<sup>®</sup> (ETHIODIZED OIL) INJECTION**.

- **Customers can order directly from Guerbet LLC by contacting Customer Service at 1-877-729-6679, between the hours of 8 a.m. and 5 p.m. (ET).**
- **LIPIODOL<sup>®</sup> ULTRA-FLUIDE is not refundable and not for resale.**

Guerbet will make reasonable attempts to fill your orders. Guerbet will be closely monitoring the distribution of **LIPIODOL<sup>®</sup> ULTRA-FLUIDE** to help manage the supply.

If you have additional questions, please contact Customer Service at 1-877-729-6679, Monday through Friday, between the hours of 8 a.m. and 5 p.m. (ET), or email [customer.service-us@guerbet-group.com](mailto:customer.service-us@guerbet-group.com). This communication and updated product information is available on the Guerbet website at <http://www.guerbet-us.com> as well as on the FDA Drug Shortage website at <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm>.

To report adverse events among patients administered, please call 1-877-729-6679 between the hours of 8 a.m. and 5 p.m. (ET), or email [medical.liaison@guerbet-group.com](mailto:medical.liaison@guerbet-group.com).

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, or regular mail, or by fax:

- Complete and submit the report **Online**: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
- Regular mail or Fax: Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

We urge you to contact our Medical Information Department at 1-877-729-6679 between the hours of 8 a.m. and 5 p.m. (ET), or email [medical.liaison@guerbet-group.com](mailto:medical.liaison@guerbet-group.com) if you have any questions about the information contained in this letter or the safe and effective use of **LIPIODOL<sup>®</sup> ULTRA-FLUIDE**.

Sincerely,

A handwritten signature in black ink that reads "Alice Lorenzo". The signature is written in a cursive, flowing style.

Alice Lorenzo, MJ, MBe, RAC  
Compliance Officer, Director of Regulatory and Quality



<b>LIPIODOL® ULTRA-FLUIDE</b> (ethyl esters of iodized fatty acids of poppy seed oil)	<b>LIPIODOL® (ETHIODIZED OIL) INJECTION</b> (ethyl esters of fatty acids of poppy seed oil)
<i>Indications and contraindications</i>	
<p>See Summary of Product Characteristics (SmPC)</p> <p><b>Please note: see SmPC sections 4.1 Therapeutic indications, 4.2 Posology and method of administration, 4.3 Contraindications, and 4.4 Special warning and precautions for use.</b></p>	<p><b>LIPIODOL®</b> is an oil-based radio-opaque contrast agent indicated for:</p> <ul style="list-style-type: none"> <li>• hysterosalpingography in adults</li> <li>• lymphography in adult and pediatric patients</li> <li>• selective hepatic intra-arterial use for imaging tumors in adults with known hepatocellular carcinoma (HCC)</li> </ul> <p><b>LIPIODOL®</b> is contraindicated in patients with hypersensitivity to Lipiodol, hyperthyroidism, traumatic injuries, recent hemorrhage or bleeding.</p> <p><b>Hysterosalpingography</b> 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.</p> <p><b>Lymphography</b> 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.</p> <p><b>Selective Hepatic Intra-arterial Use Patients with HCC</b> Lipiodol use is contraindicated in areas of the liver where the bile ducts are dilated unless external biliary drainage was performed before injection.</p>
<i>Barcode</i>	
Barcode use by <b>LIPIODOL® ULTRA-FLUIDE</b> may not register accurately in the United States scanning systems. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.	A unit of use barcode is on individual ampoules.
<i>How supplied</i>	
Box of 1 ampoule Authorization# 3400930621608: 10 mL glass ampoule, single-unit box	Lipiodol is supplied in a box of one 10 mL ampoule, NDC 60694-1901-1.
<i>Additional information</i>	
Contains a patient information leaflet	N/A