Guerbet

News

Lipiodol Transitions from Temporary Importation to Regular Supply

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Guerbet Announces Transition from Temporary Importation to Regular Supply for Lipiodol® (ethiodized oil) Injection; also introduces new glass vial container. U.S. manufacturing change from ampoules to vials reflect Guerbet's commitment to patient safety and innovation in contrast imaging.

PRINCETON, N.J., March 29, 2019 – Guerbet LLC USA, the U.S. affiliate of the global specialist in contrast media products and solutions for diagnostic and interventional imaging, today announced the end of temporary importation status for Lipiodol® (ethiodized oil) Injection and the manufactured availability of the product in the United States. Guerbet has maintained the U.S. product supply of Lipiodol® Ultra Fluid through temporary importation from Delpharm Tours, located in France. The importation remained in effect through February 2019, while Guerbet qualified a new FDA registered manufacturing site.

The newly manufactured Lipiodol® will additionally be packaged in new glass vials, as opposed to glass ampoules. These new Lipiodol® vials eliminate the risk of glass breakage and cracking problems that can be associated with use of glass ampoules.

"Guerbet has spent the last ten years investing in best practices and procedures to ensure the availability of Lipiodol® to all U.S. patients," said Massimo Carrara, Guerbet Vice President for North America. "The new FDA registered manufacturing site, along with our new packaging, ensures critical availability of the product in a preferred vial format.

Lipiodol®, is the world's first oil-based iodinated contrast agent, for both radiologists and patients.

The newly manufactured shipment of Lipiodol® in the new vial container closure system will be delivered to customers during the week of April 1, 2019.

Read the full Press Release here.

Important Safety Information for LIPIODOL® (ethiodized oil) Injection

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

• 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, or within 30 days of curettage or conization.

• 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 free iodine content and can cause hyperthyroidism or hypothyroidism in predisposed patients.

Adverse Reactions

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

• Lymphography – Cardiovascular collapse, lymphangitis, thrombophlebitis, edema or exacerbation of preexisting lymphedema, 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.

Use in Specific Population

• Pregnancy: There are no adequate and well-controlled studies of LIPIODOL® (ethiodized oil) injection effects in pregnant women. It is not known whether LIPIODOL® can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. The use of LIPIODOL® during pregnancy causes iodine transfer which may interfere with the thyroid function of the fetus and result in brain damage and permanent hypothyroidism.

• Lactation: LIPIODOL® is excreted in human milk. Avoid use of LIPIODOL® in a nursing woman because of risk of hypothyroidism in nursing infants. If breastfeeding is continued the neonate's thyroid function should be monitored.

• 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 or call 1-800-FDA-1088.

About Guerbet

Guerbet is a pioneer in the contrast-agent field, with more than 90 years' experience, and is a leader in medical imaging worldwide. It offers a comprehensive range of pharmaceutical products, medical devices, and services for diagnostic and interventional imaging to improve the diagnosis and treatment of patients. With 8% of revenue dedicated to R&D and more than 200 employees distributed across its four centres in France, Israel, and the United States, Guerbet is a substantial investor in research and innovation. Guerbet (GBT) is listed on Euronext Paris (segment B – mid caps) and generated €790 million in revenue in 2018. For more information about Guerbet, please visit www.guerbet.com

Please click here for the Lipiodol® Prescribing Information.

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