Guerbet
Contrast for Life

PRESS RELEASE

Guerbet Receives FDA Approval for a New Manufacturing Plant for Lipiodol® (ethiodized oil) Injection

Guerbet LLC, USA (February 19, 2014)

Princeton, NJ - Guerbet (GBT), the contrast agent specialist for medical imaging, today announced that it had received approval from the U.S. Food and Drug Administration (FDA) for a new manufacturing plant for Lipiodol® (ethiodized oil) Injection, in Montreal, Canada.

FDA approval provides clinicians with additional resource for patient care management. Guerbet has acquired the Ethiodol® NDA effective May 7, 2010 and since then has been working with the FDA to resume manufacturing of Ethiodol® to ensure continued availability for the U.S. patients. During this interim period, Guerbet, in conjunction with the FDA, has maintained a temporary importation of Lipiodol®, ethyl esters of iodized fatty acids of poppy seed oil, to the United States market. Lipiodol® contains the same drug components as Ethiodol®.

“After maintaining the product supply through a temporary importation program authorized by FDA, we are proud to add the United States to the list of countries where Lipiodol® is now available from an FDA approved manufacturing site”, said Yves L’Epine, CEO of the Guerbet Group.

Massimo Carrara, General Manager of Guerbet LLC in USA also commented “The approval of the new manufacturing site represents the ongoing commitment of Guerbet to consistently supply American healthcare professionals and their patients with ethiodized oil.”

Guerbet plans to transition from the temporary importation program as soon as product from the newly approved manufacturing plant will be available in the U.S.

For more information about the temporary importation program, please see the Dear Healthcare Professional Letter.

Indications and Usage

Lipiodol® is indicated for use as a radio-opaque medium for lymphography and hysterosalpingography. It contains 475 mg Iodine/mL organically combined with ethyl esters of the fatty acids (primarily as ethyl monoiodostearate and ethyl diiodostearate) of poppyseed oil. Lipiodol ® is supplied in a box of one 10mL ampoule.

Important Safety Information

NOT FOR INTRAVASCULAR, INTRATHECAL, OR INTRABRONCHIAL USE

Contraindications

Lipiodol® is contraindicated in:

- Patients hypersensitive to Iodine.
- Lymphography in patients with a right to left cardiac shunt, in patients with advanced pulmonary disease, especially those with alveolar-capillary block, and in patients who have had radiotherapy to the lungs.
- Hysterosalpingography during intrauterine pregnancy, acute pelvic inflammatory disease, marked cervical erosion, endocervicitis in the presence of intrauterine bleeding, in the immediate pre-or postmenstrual phase, or within 30 days of curettage or conization.

Warnings and Precautions

Lipiodol® may cause pulmonary embolization, hypersensitivity reactions and hyperthyroidism. The use of intralymphatic Lipiodol® presents a significant risk in patients with preexisting pulmonary disease characterized by a decrease in pulmonary diffusing capacity and/or pulmonary blood flow. This was noticed more frequently when excessive amounts of Lipiodol® have been injected, in the presence of marked lymphatic obstruction or through accidental intravenous injection.

Most Common Adverse Reactions

The most common adverse reactions are hypersensitivity reactions, foreign body reactions, and exacerbation of pelvic inflammatory disease, although infrequent. The occasional observation of pulmonary Lipiodol® embolization several hours after injection has been reported.

For more information about Lipiodol®, including Boxed WARNING, please see the Full Prescribing Information.

About Lipiodol®

Discovered in 1901 by Marcel Guerbet, Lipiodol® is approved for use in over 47 countries in Europe, Asia, Africa, Middle East, North and South America. Lipiodol® is the first and only oil-based iodinated contrast medium for radiology, launched in France in 1921.[1] It is estimated that more than 200 million of Lipiodol® doses have been administered worldwide.[2] The contrast agent was first launched in the United States in

1954 and marketed as Ethiodol®. Guerbet acquired the NDA from Nycomed, US, Inc. in 2010. The approved indications for Lipiodol® may vary between countries. Lipiodol® is available by prescription only. Lipiodol® is registered by the U.S. Patent and Trademark Office by Guerbet.

About Guerbet

A pioneer in the field of contrast agents with more than 80 years of experience, Guerbet is the only pharmaceutical group fully dedicated to medical imaging worldwide. As such it has a complete offering of contrast products for X-ray and MRI and for interventional radiology, along with a range of injectors and related medical equipment to provide improved diagnosis and treatment of patients. To promote the discovery of new products and assure future growth, Guerbet devotes significant resources to research and development every year (approximately 10% of sales).

Guerbet (GBT) is listed on NYSE Euronext Paris (Eurolist Segment B – Mid Caps) and had sales of €390 million in 2013 with a total workforce of 1,485 employees, of which 1,000 are in France.

Additional information about Guerbet is available at www.guerbet.com.

[1, 2] Data on file, Guerbet

Press Contacts

Anne-Laure Delasalle, Group Communications Director
Tel: + 33 (0)1 45 91 50 03
anne-laure.delasalle@guerbet-group.com

US Media Contact
Ted Deutsch
Tel: (609) 578-8765
ted@taftandpartners.com

This press release may contain forward-looking statements based on current assumptions and forecasts made by Guerbet Group management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performances of the company and the estimates given here. These factors include those discussed in Guerbet's public reports which are available on the Guerbet website at www.guerbet.com. The company assumes no liability whatsoever to update these forward-looking-statements or to conform them to future events or developments.

Lipiodol® is registered in U.S. Patent and Trademark Office by Guerbet and is available by prescription only.