Relevant Information for Temporary Importation Program

Due to the current critical shortage of ETHIODOL, Brand of Ethiodized Oil Injection, Guerbet is coordinating with the FDA to increase the availability of the ethyl esters of iodized fatty acids of poppy seed oil product. Please see the Dear Healthcare Professional Letter from Guerbet regarding the Agency's steps to alleviate the drug shortage.

Guerbet has acquired the Ethiodol® NDA from Nycomed US Inc. effective May 7, 2010 and is working with the FDA to resume manufacturing of Ethiodol in the near future to ensure continued availability for the US patients. During this interim period, Guerbet, in conjunction with the FDA, is initiating a temporary importation of LIPIODOL ULTRA-FLUIDE, ethyl esters of iodized fatty acids of poppy seed oil, to the United States market. LIPIODOL ULTRA-FLUIDE contains the same drug components as ETHIODOL, Brand of Ethiodized Oil Injection, (previously manufactured and marketed in the United States by Savage Laboratories, a subsidiary of Nycomed). LIPIODOL ULTRA-FLUIDE is manufactured in compliance with European Good Manufacturing Practice (GMP) regulations by Delpharm Tours (France) for Guerbet.

At this time, no other entity except Guerbet is authorized by the FDA to import or distribute LIPIODOL ULTRA-FLUIDE. Any sales of LIPIODOL ULTRA-FLUIDE ampoules from any entity other than Guerbet will be considered in violation of the Federal Food, Drug and Cosmetic Act and may be subject to enforcement action by the FDA.

Effective immediately, Guerbet will offer the following version:

 LIPIODOL ULTRA-FLUIDE
48% Iodine w/vol (i.e 480 mg Iodine/mL)
(ethyl esters of iodized fatty acids of poppy seed oil)
10mL glass ampoule
Authorization# 306 216.0
Box of 1 ampoule

LIPIODOL ULTRA-FLUIDE formulation is similar to ETHIODOL.

- 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 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 ULTRA-FLUIDE to help manage the supply.


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 a Medical Liaison. Alternatively, any adverse events that may be related to the use of these products should be reported to the FDA’s Med Watch Program by fax at 1-800-FDA-0178, by mail at Med Watch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the Med Watch website at http://www.fda.gov/safety/medwatch.

We urge you to contact our Medical Information Department at 1-877-729-6679 between the hours of 8 a.m. and 7 p.m. (ET), or email a Medical Liaison if you have any questions about the information contained in this letter or the safe and effective use of LIPIODOL ULTRA-FLUIDE.