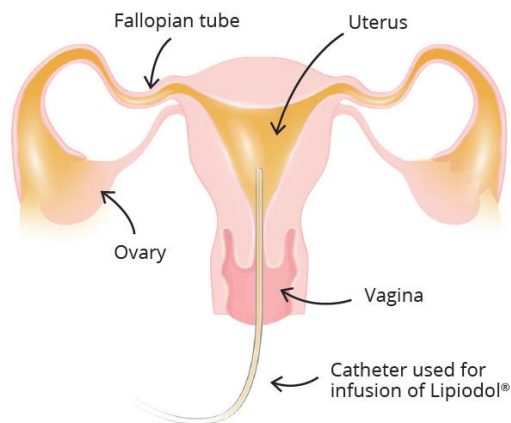


## Lipiodol® Ultra Fluid indicated for hysterosalpingography (HSG) for tubal flushing in women undergoing infertility workup in Denmark

**Villepinte (France) – July 29, 2020 - 06:00 pm CET** - Guerbet (GBT) announced today that the Danish Medicines Agency has granted approval for an extension of the indication of Lipiodol® Ultra Fluid in Denmark, where it is now indicated for hysterosalpingography (HSG) for tubal flushing in women undergoing infertility workup. Lipiodol® Ultra Fluid is the only oil-soluble contrast medium indicated for HSG.



An HSG is an x-ray procedure during which Lipiodol® Ultra Fluid is slowly infused through a catheter into the uterus to visualize the Fallopian tubes and uterine cavity. Tubal flushing characterizes the moment when Lipiodol® Ultra Fluid passes through the tubes to demonstrate tubal patency.

Tubal flushing with hysterosalpingography is a non-invasive procedure and scientific evidence suggests that it helps some women conceive.<sup>1-4</sup>

Infertility is a disease of the reproductive system, defined by the inability to achieve a pregnancy after 12 months or more of regular unprotected sexual intercourse. It is estimated that one in six couples faces infertility issues.<sup>5</sup> The fertility workup is a mandatory step in managing infertility.

Lipiodol® Ultra Fluid indication extension in Denmark is supported by an extensive regulatory dossier based on the results of a meta-analysis and 42 studies, including:

<sup>1</sup> Dreyer K et al. The therapeutic effect of hysterosalpingography in couples with unexplained subfertility: a post-hoc analysis of a prospective multi-centre cohort study. *Reprod Biomed Online*. 2019 Feb;38(2):233-239.

<sup>2</sup> Johnson NP et al. The FLUSH trial--flushing with Lipiodol® for unexplained (and endometriosis-related) subfertility by hysterosalpingography: a randomized trial. *Hum Reprod*. 2004 Sep;19(9):2043-51.

<sup>3</sup> Dreyer K et al. Oil-based or water-based contrast for hysterosalpingography in infertile women. *N Engl J Med*. 2017 May 25;376(21):2043-52.

<sup>4</sup> Wang R et al. Effectiveness on fertility outcome of tubal flushing with different contrast media: systematic review and network meta-analysis. *Ultrasound Obstet Gynecol*. 2019 Aug;54(2):172-181.

<sup>5</sup> A policy audit on fertility. Analysis of 9 EU countries. March 2017. Fertility Europe.

## Press release

1. In a single-center, randomized, controlled trial, infertile women (with unexplained infertility or endometriosis) were randomly assigned to HSG with Lipiodol® Ultra Fluid (n=73) or no HSG (n=85).<sup>2</sup>
2. In a multicenter, randomized, open-label study, the H2Oil trial, published in The New England Journal of Medicine, women were randomly assigned to either HSG with Lipiodol® Ultra Fluid (n=554) or HSG with a water-soluble contrast agent (n=554).<sup>3</sup>
3. A meta-analysis of randomized controlled trials comparing HSG with Lipiodol® Ultra Fluid to no HSG (3 studies, 382 women);<sup>2,6,7</sup> or comparing HSG with Lipiodol® Ultra Fluid with HSG with a water-soluble iodinated contrast agent (4 studies, 1,510 women).<sup>3,8-10</sup>

Lipiodol® Ultra Fluid is now approved for HSG in women undergoing infertility workup in Ireland, Hungary, the Netherlands, the Czech Republic and Denmark. In addition, Lipiodol® Ultra Fluid is currently approved for HSG in 11 additional countries (USA incl. Puerto Rico, Canada, Argentina, UK, Turkey, South-Africa, Japan, Taiwan, Thailand, Australia and New Zealand). Guerbet plans to receive authorization for HSG in women undergoing infertility workup in new countries in Europe, APAC and Latin America.

In 2016, the Guerbet Group launched its Women's Health franchise, focusing on fertility & breast cancer management in line with Guerbet's ambition to develop a women healthcare portfolio of drugs & medical devices (<https://www.guerbet.com/products-solutions/women-s-health/>).

### About Lipiodol® Ultra Fluid

---

Lipiodol® Ultra Fluid (ethyl esters of iodized fatty acids of poppyseed oil) is the only oil-based contrast agent indicated for HSG. Lipiodol® Ultra Fluid is also approved for use in interventional radiology for conventional trans-arterial chemoembolization (cTACE), for vascular embolizations and for lymphography. Lipiodol® Ultra Fluid is available in 47 countries. Indications may vary from country to country, please refer to the local Summary of Product Characteristics.

### About Guerbet

---

Guerbet is a leader in medical imaging worldwide, offering a wide range of pharmaceutical products, medical devices, digital and AI solutions for diagnostic and interventional imaging, to improve the diagnosis and treatment of patients. A pioneer since more than 90 years in the field of contrast media with over 2,800 people globally, Guerbet is continuously innovating with 9% of revenue dedicated to Research & Development and four centers in France, Israel and the United States. Guerbet (GBT) is listed on Euronext Paris (segment B – mid caps) and generated €817 million in revenue in 2019. For more information about Guerbet, please visit [www.guerbet.com](http://www.guerbet.com).

<sup>6</sup> Nugent D et al. A randomized controlled trial of tubal flushing with Lipiodol® for unexplained infertility. *Fertil Steril*. 2002; 77:173-5.

<sup>7</sup> Ogata R et al. Therapeutic efficacy of hysterosalpingography (HSG) in infertility, a prospective randomized clinical study. *Jpn J Fert Ster*. 1993, 38(1): 91-94.

<sup>8</sup> de Boer AD et al. Oil or aqueous contrast media for hysterosalpingography: a prospective, randomized, clinical study. *Eur J Obstet Gynecol Reprod Biol*. 1988;28 (1):65-68.

<sup>9</sup> Alper MM et al. Pregnancy rates after hysterosalpingography with oil- and water-soluble contrast media. *Obstet Gynecol*. 1986; 68 (1):6-9.

## Press release

<sup>10</sup> Schwabe MG et al. Hysterosalpingography with oil contrast medium enhances fertility in patients with infertility of unknown etiology. Fertil Steril. 1983; 40:604-6.

### Media Relations

---

#### **Guerbet Global**

Alize RP

Caroline Carmagnol

+33 (0)6 64 18 99 59 / [guerbet@alizerp.com](mailto:guerbet@alizerp.com)