

Femara Consent

The use of Letrozole (Femara® for Ovulation Induction)

For patients with at least one open fallopian tube and normal concentrations of sperm, the process of ovulation induction (creating an egg) helps to increase the chance of pregnancy in infertile women. Multiple medications are available to induce egg production and can range from oral medications to injectable medications.

Over the past 30 years, we have had a lot of experience using clomiphene citrate (Clomid®), which is an oral medication that binds to and blocks estrogen receptors throughout the body. As a result, the body cannot recognize its own estrogen level and works harder to make more eggs.

Clomiphene citrate lasts in the blood stream for over 30 days and can have some antiestrogenic effects on the uterus and cervix which, at times, can lower pregnancy rates. Clomid is FDA approved for use in ovulation induction; however, it is pregnancy category "X" because studies in both animal and humans show harm if it is administered while a patient is pregnant. Since Clomid® is administered prior to a person conceiving, it is considered safe for ovulation induction.

Letrozole is a medication that has been FDA approved since 1997 for the sole indication of treating breast cancer. Breast cancers are sensitive to estrogen, and Letrozole is an oral agent which lowers body estrogen levels, thereby having a favorable effect on patients with breast cancer. Over the past three years, numerous studies have been performed using Letrozole in women with infertility (without breast cancer) in hopes that lowering the estrogen level will encourage the body to make eggs (similar to Clomid). The advantage of Letrozole is that it lasts in the bloodstream for only 24 to 36 hours and does not appear to have antiestrogenic effects on the uterus or cervix. The studies to date demonstrate high pregnancy rates with the use of Letrozole, with minimal side effects and accordingly, Letrozole had been used by more and more reproductive endocrinologists.

There have been several sporadic reports regarding individual cases of fetal abnormalities described in patients who are administered Letrozole. At the present time, it is not known if this is merely due to the natural background risk of fetal abnormalities all patients have, or whether Letrozole could be a causative agent. Letrozole is pregnancy category "D," which means that well-controlled studies have shown some fetal risk; however, the risk-to-benefit ratio must be determined for each individual patient. Since Letrozole is administered during the non-pregnant stage and its short half-life allows clearance from the bloodstream before conception and organogenesis, it would appear safe to administer Letrozole as an ovulation induction agent. Until further data is released, we feel the risk-to-benefit ratio is in the favor of using Letrozole for ovulation induction.

To ensure that you are not pregnant during Letrozole administration, we require a urine pregnancy test to be negative before proceeding with treatment.

Please do not hesitate to contact us if you have any questions regarding Letrozole and its use.

By signing below, I am stating that I fully understand the risk and benefits of Letrozole use and accept the risks of Letrozole administration during my infertility treatment.

Patient Name: _____

Patient Signature: _____ Date: _____