

Women's Health Alliance, PA p/k/a  
Atrium ObGyn  
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Suite 200  
Raleigh, NC 27607

Patient Name: \_\_\_\_\_  
Chart No.: \_\_\_\_\_  
Provider: \_\_\_\_\_  
Date of Service: \_\_\_\_\_

### Consent for Femara/Letrozole

#### What is Femara?

Femara is the brand name for a drug called Letrozole that belongs to a family of aromatase inhibitors. Aromatase is the enzyme which assists in the development of estrogen. Several aromatase inhibitors including Letrozole have been approved by the FDA for use in menopausal women with breast cancer to inhibit estrogen formation.

#### How does Femara work for fertility patients?

Menstruation is a complex process that is dependent on the action of hormones released by the hypothalamus, pituitary gland and the ovary. An imbalance in the levels of these hormones can disturb normal ovulation. Taken for a brief period of time, Femara temporarily reduces estrogen levels resulting in the pituitary releasing additional messages (FSH) to the ovary, which in turn promotes ovulation.

#### When do I take Femara?

Infertility patients are usually advised to take Femara between the third and fifth days of the menstrual cycle for a total of 5 days.

#### How do I know if or when I will ovulate with Femara?

Your provider will discuss ovulation monitoring options with you. These may include the use of ovulation predictor kits or blood levels of progesterone.

#### What are the chances of multiple births with Femara?

While Femara works somewhat similar to Clomid, Femara is much shorter in its action and thus the ovary receives extra messages for a briefer time. This is the apparent explanation for the lower multiple pregnancy rates seen with Femara when compared to Clomid. Clomid has a rate of multiples, typically twins, of 5-10%, Femara is closer to 5%.

#### Is Femara associated with congenital birth defects?

One study presented at the American Society for Reproductive Medicine Meeting in 2005 reported on 150 babies born following Femara treatment compared to 36,050 babies delivered at a low risk hospital. Seven serious malformations were found in the Femara group representing a 4.7% incidence compared to a 1.8% incidence of abnormalities in the control group. The increased risk was statistically significant. A closer look at the study demonstrates multiple issues that question the validity of the results, including: 1. The group that received Femara was 5 years older than the control. 2. The twin rate was 15% in the Femara group compared to 1-2% in the control group. All of these issues are known to increase the rate of birth defects. It is statistically improper to compare groups of such different size. It may cause apparent differences when no true difference exists. Because of the multiple methodological problems, this study was never published in a peer reviewed journal.

Since this controversy, Tulandi and colleagues compared 911 babies born after treatment with either Clomid or Femara. The study was published in a leading peer reviewed fertility journal, Fertility & Sterility in June 2006. The overall malformation rate was 2.4% with Femara and 4.8% with Clomid. This is not different statistically from the generally accepted baseline risk of any birth defect in the normal population of 3-4%. With these subsequent larger and reassuring studies, many practitioners are once again prescribing Femara for fertility needs. The very short duration of action of Femara when compared to Clomid for instance, makes it quite unlikely that Femara is still circulating in one's system at the time of conception. Logically, this would make it quite unlikely for there to be any association with Femara and birth defects.

#### What side effects have been noted from taking Letrozole?

Adverse effects reported include gastrointestinal disturbances, hot flushes, headache, leg cramps and back pain.

I have the opportunity to read this information, ask questions while with my health care provider and consent to taking Femara as treatments for infertility.

Patient: \_\_\_\_\_

Date:

Witness: \_\_\_\_\_

Date: