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Consent for Letrozole Cycles

Not all patients will be using all of the medications or procedures described here.

Letrozole (Femara)

Letrozole citrate is a synthetic, oral medication that inhibits the enzyme that is responsible for the production of estrogen. As a result of decreasing estrogen feedback, the pituitary gland is stimulated to produce hormones that can then stimulate the ovary to produce follicles. Its primary use and its indication for FDA approval has been for the treatment of BREAST CANCER. Use for fertility is allowable by the FDA but is considered an off-label indication.

Side effects

Letrozole lowers the levels of estrogens in the body. This may cause symptoms of estrogen deprivation such as hot flashes (19% of patients)

Other possible symptoms (which occur in 10% or MORE of patients) include:

- Fatigue
- Nausea
- Constipation
- Back pain
- Difficulty breathing, cough
- Bone joint pain
- Other side effects, **including allergic reactions and blood clots**, have been reported but with an incidence of less than 10%

Miscarriage, Stillbirth, and Fetal congenital malformations (Birth defects)

Letrozole is considered pregnancy **Category D**. Its use is contraindicated in women who are already pregnant. Studies in rats and mice have shown a dose-related increase in some types of malformations and an increase in mortality. **Studies in human beings have not been performed but it is assumed to cause similar problems.**

HUMAN CHORIONIC GONADOTROPINS, hCG (Ovidrel, Profasi, Pregnyl)

Chorionic gonadotropins are injectable medications containing the hormone hCG which is normally produced by the placenta during pregnancy. Chorionic gonadotropins are produced by isolating and purifying these hormones from the urine of pregnant human women. There are small amounts of urinary proteins contained in the preparations. There are no known cases of disease being transmitted of one person to another through these medications.

HCG is used primarily to trigger ovulation (maturation and eventual release of the egg) in women attempting pregnancy. It is also used to help support a potential or existing pregnancy by augmenting progesterone production from the ovary after ovulation (corpus luteum) and to support follicle growth during ovulation induction.

Side effects

Recombinant hCG is given subcutaneously. Urinary hCG may be given as an intramuscular or subcutaneous injection. It is possible to have pain, rash, or swelling at the injection site. When given subcutaneously, urinary hCG may cause more local swelling, redness or irritation.

Other possible symptoms include:

- Abdominal or pelvic pain, weight gain
- Breast discomfort
- Nausea and vomiting
- Abnormal uterine bleeding
- Other side effects, **including allergic reactions**, have been reported but with an incidence of less than 1%

Miscarriage, Stillbirth, and Fetal congenital malformations (Birth defects)

The risk of miscarriage or stillbirth does not appear to be related to the use of Chorionic gonadotropins. Chorionic gonadotropins are considered pregnancy **Category X**. Combined use of hCG with PMSG (pregnant mare serum gonadotropin) has caused a high incidence of external congenital anomalies in mice. **Studies in human beings do not support an association between gonadotropins and congenital defects.**

PROGESTERONE (Crinone, Progesterone-in-oil, Prometrium, Progesterone Suppositories)

Progesterone is a steroid hormone normally produced by the ovary after ovulation and by the placenta during pregnancy. It is used primarily to induce the menses in anovulatory women and to help support the early pregnancy.

Crinone contains micronized progesterone in an oil and water emulsion called polycarbofil. Progesterone injections contain an oil base (either sesame or peanut oil).

Side effects

Possible symptoms include:

- Abdominal or pelvic pain, cramps
- Breast discomfort
- Nausea and vomiting
- Abnormal uterine bleeding
- Fatigue, drowsiness, depression
- Muscle or joint ache
- Bloating, weight gain, fluid retention. Conditions which might be influenced by this (epilepsy, migraines, asthma, cardiac or renal dysfunction) require careful observation

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- Injectable progesterone can cause pain, rash or swelling at the injection site.
- Other side effects, **such as allergic reactions**, have been reported but may be related to the vehicle (for example, peanut oil) and occur with an incidence of less than 5%.

Progesterone should not be used in patients with liver problems, undiagnosed vaginal bleeding, or with a history of clotting disorders.

Multiple pregnancy

Studies indicate that approximately 4% of the pregnancies conceived after letrozole therapy are twins. High order multiples have not been reported.

The risk of complications of pregnancy or adverse outcomes is higher with multiple pregnancies than with singleton pregnancies. These include, but are not limited to, preterm delivery, gestational diabetes, hypertensive disorders, and fetal or neonatal death.

Despite monitoring with blood tests or ultrasounds, it is not possible in most cases, to determine who will have a multiple pregnancy.

Ovarian hyperstimulation syndrome (OHSS)

OHSS is a medical complication that appears more commonly after the use of fertility medications. **This complication has not yet been reported with letrozole.** In its severe form, OHSS is characterized by ovarian enlargement, accumulation of fluid in the abdomen (ascites) , chest cavity (pleural effusion), or around the heart (pericardial effusion). There are abnormalities in blood chemistries (electrolytes), abnormal function of the liver and/or kidneys, and increased risk for blood clots.

Patients may notice abdominal discomfort, nausea, vomiting, weight gain, decreased urine output, shortness of breath, difficulty breathing, or pelvic pain.

Patients have died as a result of complications of OHSS usually due to blood clots.

Despite monitoring with blood tests or ultrasounds, it is not possible in most cases, to prevent the occurrence of OHSS.

The risk of OHSS is higher if the patient achieves pregnancy and especially with multiple pregnancy.

Cancer

Some studies have postulated an association between the use of fertility medications and the subsequent development of epithelial ovarian cancer. Other studies have not demonstrated an association. Letrozole has not been associated with the development of ovarian cancer.

I understand that use of this medication may not be successful in causing ovulation or producing a pregnancy. A pregnancy that does occur may not result in the birth of a live born infant.

I acknowledge that I have read the above consent in its entirety and have had any questions answered completely and to my satisfaction.

I understand the risks, consequences, and potential benefits of letrozole use.

My signature below indicates my consent to the use of letrozole and that I am exercising independent judgement as to the use of such fertility enhancing medications. I understand that I may withdraw my consent at any time.

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