

**RANDY S. MORRIS M.D.**  
BOARD CERTIFIED REPRODUCTIVE ENDOCRINOLOGY  
AND INFERTILITY

**Medications Consent**

**HUMAN MENOPAUSAL GONADOTROPINS, hMG** (Repronex, Pergonal, Humegon, Fertinex, Metrodin)

Gonadotropins are injectable medications containing primarily the hormones FSH (Follicle Stimulating Hormone) and LH (Luteinizing Hormone). Menopausal gonadotropins are produced by isolating and purifying these hormones from the urine of human post-menopausal 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.

**RECOMBINANT GONADOTROPINS** (Gonal-F, Follistim)

These gonadotropins are produced through recombinant DNA technology. The genes for human FSH have been isolated then inserted into Chinese hamster ovary cells. The cells are then induced to produce high amounts of FSH, which is then purified for use as an injectable medication. Recombinant FSH has no detectable LH activity.

**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 gonadotropins are given subcutaneously. Menopausal gonadotropins 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, menopausal gonadotropins may cause more local swelling, redness or irritation. Other possible symptoms include:

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

Cancer

Some studies have postulated an association between the use of fertility medications, including gonadotropins and the subsequent development of epithelial ovarian cancer. Other studies have not demonstrated an association. The American Society of Reproductive Medicine Practice Committee recommends that physicians caution patients about the possibility of this risk.

There appears to be no increased risk of breast cancer associated with use of these medications.

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

The risk of miscarriage or stillbirth does not appear to be related to the use of gonadotropins. 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.**

**GONADOTROPIN RELEASING HORMONE AGONIST - GnRHa** (Lupron, Synarel, Zoladex)

GnRH agonists are synthetic protein derivatives of the human hypothalamic hormone GnRH. They are administered by injection (Lupron) or inhalation (Synarel). When given continuously at therapeutic doses, GnRH agonists first stimulate then inhibit the release of the pituitary hormones which normally stimulate

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the ovaries. Without pituitary stimulation, the ovaries stops development of follicles and levels of ovarian hormones such as estrogen drop to low levels. These medications are commonly used to reduce the likelihood of premature ovulation in ART cycles. They are also used to treat endometriosis, fibroids, and pelvic pain.

**GONADOTROPIN RELEASING HORMONE ANTAGONIST – GnRH ant (Ganirelix, Cetrotide)**

GnRH antagonists are synthetic protein derivatives of the human hypothalamic hormone GnRH. They function by blocking the effect of naturally produced GnRH. The result is a rapid decrease in the pituitary hormones, which continues for as long as the medication is administered.

Side effects

Since the production of estrogens from the ovaries is reduced to post-menopausal levels, any post-menopausal symptoms may occur. This commonly includes hot flashes (55%) but may also include headache (7%), vaginal dryness and irritation, decreased libido, and lethargy. Injections can cause pain, swelling, itching, or irritation at the injection sites. Inhaled medications can cause nasal irritation.

During the initial stimulation phase of GnRH agonist use, ovarian cyst formation may occur. Also, exacerbation of estrogen related medical problems such as endometriosis or fibroids might occur. These problems may require extension of the length of time for medication use or necessitate surgical treatment.

Numerous other side effects have been reported with low frequencies and include but are not limited to:

Abdominal or pelvic pain, cramps	Nausea and vomiting	Abnormal uterine bleeding
Allergic reaction	Bloating, weight gain, fluid retention.*	

\*Conditions which might be influenced by this (epilepsy, migraines, asthma, cardiac or renal dysfunction) require careful observation

Use during pregnancy

Both GnRH agonists and antagonists are rated pregnancy **Category "X"** Its use is contraindicated in women who are already pregnant. There are reports in the scientific literature of women who inadvertently took GnRH agonists during pregnancy. There is a suggestion that this may increase the risk of miscarriage. **There is no suggestion from the medical literature that agonist or antagonist use increases the risk of fetal malformations.**

**PROGESTERONE** (Crinone, Endometrin, Progesterone-in-oil, 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 polycarbophil. Progesterone injections contain an oil base (either sesame or peanut oil).

Side effects

Possible symptoms include:

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

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

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Multiple pregnancy

When attempting pregnancy using gonadotropins with intercourse or intrauterine insemination, we have seen the following risks for multiple pregnancy. :

	<b>Age &lt; 30</b>	<b>30-34</b>	<b>35-37</b>	<b>38-40</b>	<b>41-42</b>	<b>&gt; 42 y/o</b>
Twins	37%	22%	12%	9%	7%	0%
Triplets or more	21%	10%	3%	5%	0%	0%

When using these medications for in-vitro fertilization procedures (ART), the risk for multiple pregnancy is primarily related to the number of eggs or embryos transferred to the uterus rather than direct effects of the medicine.

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 such as gonadotropins. The estimated incidence of this complication after gonadotropin therapy is 1 in 500 to 1 in 1000 patients. Patients at higher risk include women who are young, thin, have a history of exaggerated response to gonadotropins, and women with polycystic ovary syndrome.

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.

I understand that use of these medications 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 these medications.

My signature below indicates my consent to the use of the medications and procedures and that I am exercising independent judgement as to the use of such fertility enhancing medications.