Conjoint Annual Meeting

ASRM & CFAS 2005 Montreal

First Announcement

October 15–19, 2005

Montreal, Quebec

Reproductive Medicine 2005 –
Expanding the Borders and Meeting New Challenges

American Society for Reproductive Medicine
61st Annual Meeting

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Canadian Fertility & Andrology Society
51st Annual Meeting

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Reproductive Medicine 2005 – Expanding the Borders and Meeting New Challenges
Palais des Congrès
Montreal, Quebec, Canada • October 15–19, 2005

The Presidents' Message

It is our pleasure to invite you to the 61st Annual Meeting of the American Society for Reproductive Medicine (ASRM) and the 51st Annual Meeting of the Canadian Fertility and Andrology Society (CFAS). Traditionally, our Societies meet conjointly whenever the ASRM meeting is held in Canada. In 1986, the first conjoint meeting was held in Toronto. The 2005 meeting in Montreal, Quebec, Canada, October 15-19, marks our fourth conjoint meeting.

Themed "Reproductive Medicine 2005 - Expanding the Borders and Meeting New Challenges," the meeting will offer an extensive variety of lectures, symposia, and events highlighting the changes and advances in all aspects of reproductive medicine.

We hope you will join us in Montreal for what promises to be an outstanding educational experience!

Robert S. Schenken, M.D.
ASRM President, 2004-2005

John Grantmyre, M.D.
CFAS President, 2004-2005

The American Society for Reproductive Medicine is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

Dates to Remember

February 2005: Visit www.asrm.org for Annual Meeting Information & Call for Abstracts and Videos
***Call for Abstracts and Videos Ad will also appear in the January 2005 through April 2005 issues of* Fertility and Sterility.**

June 2005: Visit www.asrm.org for the Preliminary Program and Registration Information

Abstract Deadlines

March 4, 2005: Online abstract submitter available at www.asrm.org

May 2, 2005: Deadline for receipt of abstracts*

***Abstracts must be received electronically through the web-based program by 11:59 p.m. Eastern Standard Time.**
No faxed, emailed, or mailed submissions will be accepted.

To receive a printed copy of the 2005 Preliminary Program, please contact ASRM.
(205) 978-5000 phone • (205) 978-5005 fax • Email: asrm@asrm.org

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Precisely right for her™

The only **prefilled** and **ready-to-use** multi-dose FSH pen

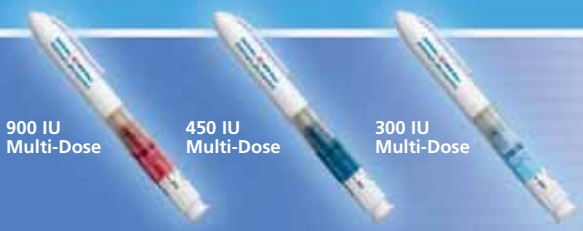
- Designed to facilitate precise FSH dosing
- No reconstitution, no cartridge loading

Gonal-f® RFF Pen (follitropin alfa injection) should only be prescribed by physicians who are thoroughly familiar with infertility problems and their management. Gonal-f® RFF Pen is a potent gonadotropic substance capable of causing ovarian hyperstimulation syndrome (OHSS) in women with or without pulmonary or vascular complications. Gonal-f® RFF Pen is contraindicated in women who exhibit prior hypersensitivity to recombinant FSH preparations, primary gonadal failure, uncontrolled thyroid or adrenal dysfunction and pregnancy. Women who are nursing should not use Gonal-f® RFF Pen. Side effects in women using Gonal-f® RFF Pen for infertility treatment may include headache, abdominal pain, enlarged abdomen and injection site bruising. Reports of multiple births have been associated with Gonal-f® RFF Pen treatment. For complete product details, see the full prescribing information.

www.fertilitylifelines.com

RFF: Revised Formulation Female.

See brief summary of prescribing information on adjacent page.



GONAL-f™ RFF Pen
(FOLLITROPIN ALFA INJECTION)

The peace-of-mind FSH℠

GONAL-f® RFF Pen (follitropin alfa injection)
*revised formulation female
Brief Summary of prescribing information

Gonal-f® RFF Pen (follitropin alfa injection) is a human follicle stimulating hormone (FSH) preparation of recombinant DNA origin, which consists of two non-covalently linked, non-identical glycoproteins designated as the α- and β-subunits. Gonal-f® RFF Pen contains no luteinizing hormone (LH) activity. Based on available data derived from physico-chemical tests and bioassays, follitropin alfa and follitropin beta, another recombinant follicle stimulating hormone product, are indistinguishable.

INDICATIONS AND USAGE

Gonal-f® RFF Pen (follitropin alfa injection) is indicated for the induction of ovulation and pregnancy in the oligo-anovulatory infertile patient in whom the cause of infertility is functional and not due to primary ovarian failure. Gonal-f® RFF Pen is also indicated for the development of multiple follicles in the ovulatory patient participating in an Assisted Reproductive Technology (ART) program.

CONTRAINDICATIONS

Gonal-f® RFF Pen (follitropin alfa injection) is contraindicated in women who exhibit: 1. Prior hypersensitivity to recombinant FSH preparations or one of their excipients. 2. High levels of FSH indicating primary gonadal failure. 3. Uncontrolled thyroid or adrenal dysfunction. 4. Sex hormone dependent tumors of the reproductive tract and accessory organs. 5. An organic intracranial lesion such as a pituitary tumor. 6. Abnormal uterine bleeding of undetermined origin. 7. Ovarian cyst or enlargement of undetermined origin, not due to polycystic ovary syndrome. 8. Pregnancy.

WARNINGS

Gonal-f® RFF Pen (follitropin alfa injection) should only be used by physicians who are thoroughly familiar with infertility problems and their management.

Gonal-f® RFF Pen is a potent gonadotropic substance capable of causing Ovarian Hyperstimulation Syndrome (OHSS) in women with or without pulmonary or vascular complications. Gonadotropin therapy requires a certain time commitment by physicians and supportive health professionals, and requires the availability of appropriate monitoring facilities (see "Precautions/Laboratory Tests"). Safe and effective use of Gonal-f® RFF Pen in women requires monitoring of ovarian response with serum estradiol and vaginal ultrasound on a regular basis. The lowest effective dose should be used.

Overstimulation of the Ovary During FSH Therapy:

Ovarian Enlargement: Mild to moderate uncomplicated ovarian enlargement which may be accompanied by abdominal distention and/or abdominal pain occurs in approximately 20% of those treated with urofollitropin and hCG, and generally regresses without treatment within two or three weeks. Careful monitoring of ovarian response can further minimize the risk of overstimulation. If the ovaries are abnormally enlarged on the last day of Gonal-f® RFF Pen therapy, hCG should not be administered in this course of therapy. This will reduce the chances of development of Ovarian Hyperstimulation Syndrome.

Ovarian Hyperstimulation Syndrome (OHSS): OHSS is a medical event distinct from uncomplicated ovarian enlargement. Severe OHSS may progress rapidly (within 24 hours to several days) to become a serious medical event. It is characterized by an apparent dramatic increase in vascular permeability which can result in a rapid accumulation of fluid in the peritoneal cavity, thorax, and potentially, the pericardium. The early warning signs of development of OHSS are severe pelvic pain, nausea, vomiting, and weight gain.

OHSS occurred in 6 of 83 (7.2%) Gonal-f® RFF treated women in Study 22240 (ovulation induction); none were classified as severe. In Study 21884 (ART), OHSS occurred in 11 of 237 (4.6%) Gonal-f® RFF treated women and 1 (0.42%) was classified as severe. OHSS may be more severe and more protracted if pregnancy occurs. OHSS develops rapidly; therefore, patients should be followed for at least two weeks after hCG administration. If there is evidence that OHSS may be developing prior to hCG administration, the hCG must be withheld. If severe OHSS occurs, treatment must be stopped and the patient should be hospitalized.

Pulmonary and Vascular Complications:

Serious pulmonary conditions (e.g., atelectasis, acute respiratory distress syndrome and exacerbation of asthma) have been reported. In addition, thromboembolic events both in association with, and separate from Ovarian Hyperstimulation Syndrome have been reported. Intravascular thrombosis and embolism can result in reduced blood flow to critical organs or the extremities. In rare cases, pulmonary complications and/or thromboembolic events have resulted in death.

Multiple Births: Reports of multiple births have been associated with Gonal-f® RFF treatment. In Study 22240 for women receiving Gonal-f® RFF over three treatment cycles, 20% of live births were multiple births. In Study 21884, 35.1% of live births were multiple births in women receiving Gonal-f® RFF. The rate of multiple births is dependent on the number of embryos transferred. The patient should be advised of the potential risk of multiple births before starting treatment.

PRECAUTIONS

General: Careful attention should be given to the diagnosis of infertility in candidates for Gonal-f® RFF Pen (follitropin alfa injection) therapy (see "Indications and Usage/ Selection of Patients").

Information for Patients: Prior to therapy with Gonal-f® RFF Pen, patients should be informed of the duration of treatment and monitoring of their condition that will be required. The risks of ovarian hyperstimulation syndrome and multiple births in women (see **WARNINGS**) and other possible adverse reactions (see "**ADVERSE REACTIONS**") should also be discussed.

A 'Patient's Information Leaflet' is provided for patients prescribed Gonal-f® RFF Pen.

Laboratory Tests: In most instances, treatment of women with Gonal-f® RFF Pen results only in follicular recruitment and development. In the absence of an endogenous LH surge, hCG is given when monitoring of the patient indicates that sufficient follicular development has occurred. This may be estimated by ultrasound alone or in combination with measurement of serum estradiol levels. The combination of both ultrasound and serum estradiol measurement are useful for monitoring the development of follicles, for timing of the ovulatory trigger, as well as for detecting ovarian enlargement and minimizing the risk of the Ovarian Hyperstimulation Syndrome and multiple gestation. It is recommended that the number of growing follicles be confirmed using ultrasonography because plasma estrogens do not give an indication of the size or number of follicles. The clinical confirmation of ovulation, with the exception of pregnancy, is obtained by direct and indirect indices of progesterone production. The indices most generally used are: 1. A rise in basal body temperature; 2. Increase in serum progesterone; and 3. Menstruation following a shift in basal body temperature.

When used in conjunction with the indices of progesterone production, sonographic visualization of the ovaries will assist in determining if ovulation has occurred. Sonographic evidence of ovulation may include: 1. Fluid in the cul-de-sac; 2. Ovarian stigmata; 3. Collapsed follicle; and 4. Secretory endometrium.

Accurate interpretation of the indices of follicle development and maturation require a physician who is experienced in the interpretation of these tests.

Drug Interactions: No drug/drug interaction studies have been performed.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term studies in animals have not been performed to evaluate the carcinogenic potential of Gonal-f® RFF Pen. However, follitropin alfa showed no mutagenic activity in a series of tests performed to evaluate its potential genetic toxicity including, bacterial and mammalian cell mutation tests, a chromosomal aberration test and a micronucleus test. Impaired fertility has been reported in rats, exposed to pharmacological doses of follitropin alfa (≥40 IU/kg/day) for extended periods, through reduced fecundity.

Pregnancy: Pregnancy Category X. See CONTRAINDICATIONS.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in the nursing infant from Gonal-f® RFF Pen, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

The safety of Gonal-f® RFF was examined in two clinical studies [(one ovulation induction study (n=83) and one study in ART (n=237)].

Adverse events (without regard to causality assessment) occurring in at least 2.0% of patients in Study 22240 (ovulation induction) are listed in Table 1.

Table 1: Safety Profile in Ovulation Induction Study 22240

Body System Preferred Term	**Patients (%) Experiencing Events Treatment cycles = 176* n=83†**
Central and Peripheral Nervous System	
Headache	22 (26.5%)
Dizziness	2 (2.4%)
Migraine	3 (3.6%)
Gastro-intestinal System	
Abdominal Pain	10 (12.0%)
Nausea	3 (3.6%)
Flatulence	3 (3.6%)
Diarrhea	3 (3.6%)
Toothache	3 (3.6%)
Dyspepsia	2 (2.4%)
Constipation	2 (2.4%)
Stomatitis Ulcerative	2 (2.4%)
Neoplasm	
Ovarian Cyst	3 (3.6%)
Reproductive, Female	
Ovarian Hyperstimulation	6 (7.2%)
Breast Pain Female	5 (6.0%)
Vaginal Haemorrhage	5 (6.0%)
Gynecological-related pain	2 (2.4%)
Uterine haemorrhage	2 (2.4%)
Respiratory System	
Sinusitis	5 (6.0%)
Pharyngitis	6 (7.2%)
Rhinitis	6 (7.2%)
Coughing	2 (2.4%)
Application Site	
Injection Site Pain	4 (4.8%)
Injection Site Inflammation	2 (2.4%)
Body as a Whole – General	
Back Pain	3 (3.6%)
Pain	2 (2.4%)
Fever	2 (2.4%)
Hot Flushes	2 (2.4%)
Malaise	2 (2.4%)
Skin and Appendages	
Acne	3 (3.6%)
Urinary System	
Micturition Frequency	2 (2.4%)
Cystitis	2 (2.4%)
Resistance Mechanism	
Infection viral	2 (2.4%)

* up to 3 cycles of therapy

† total patients treated with Gonal-f® RFF

Headache occurred in greater than 20% of patients receiving Gonal-f® RFF in this study.

Adverse events (without regard to causality assessment) occurring in at least 2.0% of patients in Study 21884 (ART) are listed in Table 2.

Table 2: Safety Profile in Assisted Reproductive Technologies Study 21884

Body System Preferred Term	**Patients (%) Experiencing Events n=237†**
Gastro-intestinal System	
Abdominal Pain	55 (23.2%)
Nausea	19 (8.0%)
Body as a Whole – General	
Abdomen Enlarged	33 (13.9%)
Pain	7 (3.0%)
Central and Peripheral Nervous System	
Headache	44 (18.6%)
Dizziness	5 (2.1)%
Application Site Disorders	
Injection site bruising	23 (9.7%)
Injection site pain	13 (5.5%)
Injection site inflammation	10 (4.2%)
Injection site reaction	10 (4.2%)
Application site oedema	6 (2.5%)
Reproductive, Female	
Ovarian Hyperstimulation	11 (4.6%)
Intermenstrual Bleeding	9 (3.8%)

† total patients treated with Gonal-f® RFF

Headache and abdomen enlargement occurred in more than 10% of patients and abdominal pain occurred in more than 20% of patients.

The following medical events have been reported subsequent to pregnancies resulting from Gonal-f® RFF therapy in controlled clinical studies: spontaneous abortion ectopic pregnancy, premature labor and postpartum fever. There have been infrequent reports of ovarian neoplasms, both benign and malignant, in women who have undergone multiple drug regimens for ovulation induction; however, a causal relationship has not been established.

Post Marketing Reports

During post-market surveillance, reports of hypersensitivity reactions including anaphylactoid reactions have been reported with the use of Gonal-f® RFF.

OVERDOSAGE

Aside from possible ovarian hyperstimulation and multiple gestations (see "**WARNINGS**"), there is no information on the consequences of acute overdosage with Gonal-f® RFF Pen (follitropin alfa injection).

HOW SUPPLIED

Gonal-f® RFF Pen (follitropin alfa injection) is a disposable, prefilled multiple-dose delivery system containing a sterile, ready-to-use liquid formulation of follitropin alfa. Each Gonal-f® RFF Pen is filled with 415 IU, 568 IU, or 1026 IU follitropin alfa to deliver a minimum total of 300 IU in 0.5 mL, 450 IU in 0.75 mL, or 900 IU in 1.5 mL, respectively. Each Pen is supplied in a carton containing 29G x 1/2 inch disposable needles to be used for administration.

Store the Gonal-f® RFF Pen refrigerated (2°-8°C/36°-46°F) until dispensed. Upon dispensing, the patient may store the pen refrigerated (2°-8°C/36°-46°F) until the expiration date, or at room temperature (20°-25°C/68°-77°F) for up to one month or until the expiration date, whichever occurs first. After the first injection, the pen may be stored refrigerated (2°-8°C/36°-46°F) or at room temperature (20°-25°C/68°-77°F) for up to 28 days. Protect from light. Do not freeze. Discard unused material after 28 days.

Rx only

Manufactured for: SERONO, INC., Rockland, MA 02370 U.S.A. Revised: May 2004

For further information, non-US residents contact Serono International S.A., Chemin des Mines 15bis, P.O. Box 54, 1211 Geneva 20, Switzerland. US residents contact Serono Inc. One Technology Place, Rockland, MA 02370, USA. Gonal-f is a registered trademark of the Serono Group of Companies. © 2004 Serono International S.A. All rights reserved.

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GONAL-f™ RFF Pen
(FOLLITROPIN ALFA INJECTION)