A BROAD PORTFOLIO OF PRODUCTS

Menopur®
(menotropins for injection)

Endometrin®
(progesterone) Vaginal Insert 100mg

Ganirelix Acetate Injection 250mcg/0.5mL

Novarel®
(chorionic gonadotropin for injection, USP)

InVoCell®

FERRING
PHARMACEUTICALS

US-RMMH-2000196

MENOPUR (menotropins for injection)

INDICATION FOR USE
- MENOPUR® (menotropins for injection), administered subcutaneously, is indicated for the development of multiple follicles and pregnancy in the ovulatory patients participating in an Assisted Reproductive Technology (ART) program.

IMPORTANT SAFETY INFORMATION
- MENOPUR is contraindicated in women who have: a high FSH level indicating primary ovarian failure, presence of uncontrolled non-gonadal endocrinopathies, tumors of the pituitary gland or hypothalamus, sex hormone dependent tumors of the reproductive tract and accessory organs, abnormal uterine bleeding of undetermined origin, ovarian cysts or enlargement of undetermined origin, not due to polycystic ovary syndrome, or prior hypersensitivity to menotropins or MENOPUR. MENOPUR is not indicated in women who are pregnant and may cause fetal harm when administered to a pregnant woman
- MENOPUR should only be used by physicians who are thoroughly familiar with infertility problems. MENOPUR is a potent gonadotropic substance capable of causing Ovarian Hyperstimulation Syndrome (OHSS), with or without pulmonary or vascular complications, in women undergoing therapy for infertility. Ovarian torsion has been reported after gonadotropin treatment. Serious pulmonary conditions and thromboembolic events have been reported with MENOPUR. There have been infrequent reports of ovarian neoplasms with MENOPUR. Multiple pregnancies, spontaneous abortion, congenital malformations and ectopic pregnancies have occurred following treatment with MENOPUR.
- The most common adverse reactions (≥2%) in ART include: abdominal cramps; abdomen enlarged; abdominal pain; headache; injection site pain and reaction; injection site inflammation; OHSS.

Prescribing Information

ENDOMETRIN (progesterone) Vaginal Insert

INDICATION FOR USE
- ENDOMETRIN® (progesterone) Vaginal Insert is indicated to support embryo implantation and early pregnancy by supplementation of corpus luteal function as part of an Assisted Reproductive Technology (ART) treatment program for infertile women.

IMPORTANT SAFETY INFORMATION
- ENDOMETRIN should not be used in individuals with any of the following conditions: previous allergic reactions to progesterone or any of the ingredients of ENDOMETRIN, undiagnosed vaginal bleeding, known missed abortion or ectopic pregnancy, liver disease, known or suspected breast cancer, active arterial or venous thromboembolism or severe thrombophlebitis, or a history of these events.
- The physician should be alert to earliest signs of myocardial infarction, cerebrovascular disorders, arterial or venous thromboembolism (venous thromboembolism or pulmonary embolism), thrombophlebitis, or retinal thrombosis. ENDOMETRIN should be discontinued if any of these are suspected.
- Patients with a history of depression need to be closely observed. Consider discontinuation if symptoms worsen.
- ENDOMETRIN should not be recommended for use with other vaginal products (such as antifungal products) as this may alter progesterone release and absorption from the vaginal insert.
- The most common adverse reactions reported (greater than 5%) were post-oocyte retrieval pain, abdominal pain, nausea, and ovarian hyperstimulation syndrome.

Prescribing Information

GANIRELIX ACETATE INJECTION

INDICATION FOR USE
- Ganirelix acetate injection is indicated for the inhibition of premature LH surges in women undergoing controlled ovarian hyperstimulation.

IMPORTANT SAFETY INFORMATION
- Ganirelix acetate injection is contraindicated under the following conditions: Known hypersensitivity to ganirelix acetate or to any of its components, Known hypersensitivity to GnRH or any other GnRH analog, Known or suspected pregnancy.
- Ganirelix acetate injection should be prescribed by physicians who are experienced in infertility treatment. Before starting treatment with ganirelix acetate, pregnancy must be excluded. Safe use of ganirelix acetate during pregnancy has not been established.
- Special care should be taken in women with signs and symptoms of active allergic conditions.
- Cases of hypersensitivity reactions, including anaphylactoid reactions, have been reported, as early as with the first dose, during postmarketing surveillance. In the absence of clinical experience, ganirelix acetate treatment is not advised in women with severe allergic conditions.
- The packaging of this product contains natural rubber latex which may cause allergic reactions.
- Most commonly reported adverse reactions (≥ 1%) reported in clinical trials were: Abdominal Pain (gynecological), Death Fetal, Headache, Ovarian Hyperstimulation Syndrome, Vaginal Bleeding, Injection Site Reaction, Nausea, Abdominal Pain (gastrointestinal).
- During post marketing surveillance, rare cases of hypersensitivity reactions, including anaphylactoid reactions, have been reported, as early as with the first dose.
- Major and minor congenital abnormalities have been reported in clinical follow-up studies of newborns of women administered ganirelix acetate injection. The causal relationship between these congenital anomalies and ganirelix acetate is unknown.

Prescribing Information

NOVAREL(chorionic gonadotropin for injection, USP)

INDICATION FOR USE
- NOVAREL® is indicated for the induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pre-treated with human menotropins.

IMPORTANT SAFETY INFORMATION
- NOVAREL should not be used in patients with prior allergic reaction to HCG. HCG may cause fetal harm when administered to a pregnant woman.
- NOVAREL should be used in conjunction with human menopausal gonadotropins only by physicians experienced with infertility problems who are familiar with the criteria for patient selection, contraindications, warnings, precautions, and adverse reactions described in the package insert for menotropins. The principal serious adverse reactions during this use are: (1) Ovarian hyperstimulation, a syndrome of sudden ovarian enlargement, ascites with or without pain, and/or pleural effusion; (2) Enlargement of preexisting ovarian cysts or rupture of ovarian cysts with resultant hemoperitoneum; (3) Multiple births, and (4) Arterial thromboembolism.
- Anaphylaxis has been reported with urinary-derived HCG products.
- Since androgens may cause fluid retention, HCG should be used with caution in patients with cardiac or renal disease, epilepsy, migraine, or asthma.
- HCG can cross react in the radioimmunoassay of gonadotropins, especially luteinizing hormone. Each individual laboratory should establish the degree of cross reactivity with their gonadotropin assay. Physicians should make the laboratory aware of patients on HCG if gonadotropin levels are requested.
- Defects of forelimbs and of the central nervous system, as well as alterations in sex ratio, have been reported in mice on combined gonadotropin and HCG regimens. The dose of gonadotropin used was intended to induce superovulation. No mutagenic effect has been clearly established in humans.
- It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised when HCG is administered to a nursing woman.
- Adverse reactions include headache, irritability, restlessness, depression, fatigue, edema, precocious puberty, gynecomastia, pain at the site of injection. Hypersensitivity reactions both localized and systemic in nature, including erythema, urticaria, rash, angioedema, dyspnea and shortness of breath, have been reported. The relationship of these allergic-like events to the polypeptide hormone or the diluent containing benzyl alcohol is not clear.

Prescribing Information

INVOCELL Intravaginal Culture System

INDICATIONS FOR USE
INVOCELL® Intravaginal Culture System consists of the INVOCELL Culture Device and the INVOCELL Retention Device.

The Culture Device is indicated for use in preparing, holding, and transferring human gametes or embryos during In Vitro Fertilization/Intravaginal Culture (IVF/IVC) and Intra-Cytoplasmic Sperm Injection Fertilization/Intravaginal Culture (ICSI/IVC) procedures.

The Retention Device is indicated for use during the incubation period to aid in retention of the Culture Device in the vaginal cavity.

The Culture and Retention Devices are not indicated for incubation periods exceeding 72 hours.

SELECT IMPORTANT SAFETY INFORMATION
- Culture and Retention Devices should not be used in patients with the inability to tolerate placement or wearing of a device within the vaginal cavity.
- Culture and Retention Devices are single use only. Do not use if product or package appears damaged.
- Do not use Culture Device in patients with hypersensitivity to medical grade silicone or polystyrene or in patients with a severe case of vaginitis or with a history of toxic shock syndrome. Evaluate patients for any recent pelvic surgery to assure it will not affect intravaginal culture procedure.
- Proper handling is extremely important to safe and effective use of Culture Device. Do not begin clinical use of INVOCELL Intravaginal Culture System without establishing competency by reading and practicing Instructions for Use.
- It is recommended that INVOCELL Intravaginal Culture System be utilized with a mild ovarian stimulation protocol. The recommended upper limit on number of oocytes or ICSI fertilized embryos to be placed in Culture Device is seven.
- Verify Culture Device is correctly locked before placement in vaginal cavity.
- Patients should avoid any activity that may alter temperature of vaginal cavity and should avoid manipulation and removal of Culture and Retention Devices while in place.

Instructions For Use