

Fertiedge FSH 75 Injection

Product Information: Urofollitropin (75 IU) Injection

Composition:

Each vial contains:

- **Urofollitropin: 75 IU**
(Highly purified human follicle-stimulating hormone [FSH] obtained from postmenopausal women's urine.)
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Pharmacological Class:

- **Gonadotropin:** A purified form of follicle-stimulating hormone (FSH).
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Indications:

Urofollitropin injection is indicated for:

1. **Female Infertility:**
 - Stimulation of ovarian follicle growth in women undergoing assisted reproductive technologies (ART) like in-vitro fertilization (IVF) or ovulation induction.
 - Treatment of anovulation (absence of ovulation) in women unresponsive to clomiphene citrate.
2. **Male Infertility:**
 - Used in combination with human chorionic gonadotropin (hCG) for spermatogenesis in men with hypogonadotropic hypogonadism.

Mechanism of Action:

- Urofollitropin mimics the action of endogenous FSH, stimulating the growth and maturation of ovarian follicles in females.
 - In males, it stimulates Sertoli cells, promoting spermatogenesis when used with hCG.
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Dosage and Administration:

- **Dosage for Females:**
 - **Ovulation Induction:** 75–150 IU daily, starting on Day 2 or 3 of the menstrual cycle. The dose may be adjusted based on ovarian response, monitored by ultrasound and estradiol levels.
 - **ART (e.g., IVF):** Initial dose of 150–225 IU per day, adjusted as needed.
 - **Dosage for Males:**
 - Typically 75–150 IU two to three times weekly, combined with hCG.
 - **Administration:**
 - **Subcutaneous or Intramuscular Injection:** Administer under medical supervision.
 - Reconstitute the lyophilized powder with the provided diluent before injection.
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Contraindications:

- **Pregnancy and Lactation:**
Contraindicated in pregnancy (Category X) and breastfeeding.
 - **Ovarian, Uterine, or Breast Tumors:**
Avoid use in patients with hormone-sensitive malignancies.
 - **Ovarian Enlargement or Cysts:** Exclude ovarian cysts unrelated to polycystic ovary syndrome (PCOS).
 - **Primary Gonadal Failure:** Ineffective in patients with primary ovarian or testicular failure.
 - **Hypersensitivity:** Allergy to urofollitropin or any excipients.
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Warnings and Precautions:

1. **Ovarian Hyperstimulation Syndrome (OHSS):**
 - Monitor closely for signs of OHSS, including abdominal pain, weight gain, and fluid retention.
 2. **Multiple Pregnancies:**
 - Increased risk of twins or higher-order multiples; monitor follicular development carefully.
 3. **Thromboembolic Events:**
 - Use cautiously in patients with a history of thrombosis or risk factors for thromboembolism.
 4. **Monitoring:**
 - Regular monitoring with ultrasound and serum estradiol levels to avoid overstimulation or OHSS.
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Adverse Effects:

- **Common Side Effects:**
 - Headache
 - Nausea
 - Abdominal discomfort or bloating

- Injection site reactions (redness, swelling, or pain)
 - **Serious Side Effects:**
 - Ovarian Hyperstimulation Syndrome (OHSS)
 - Thromboembolic events
 - Pelvic pain or severe abdominal swelling
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Drug Interactions:

- **Gonadotropin-Releasing Hormone Agonists/Antagonists:**
 - May be co-administered in ART protocols; adjust doses accordingly.
 - **hCG:**
 - Often used as a trigger injection after urofollitropin to induce ovulation.
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Use in Special Populations:

- **Pregnancy:** Contraindicated.
 - **Lactation:** Not recommended; safety in breastfeeding is not established.
 - **Elderly:** Not indicated for postmenopausal women.
 - **Pediatrics:** Not indicated for use in children.
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Storage:

- Store the vial and diluent at 2°C to 8°C (refrigerated).
- Protect from light.
- Once reconstituted, use immediately or within the time specified by the manufacturer (typically 24 hours if stored under appropriate conditions).

Packaging:

- **Available as a lyophilized powder in a vial with an accompanying sterile diluent for reconstitution.**
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Patient Instructions:

- 1. Administer the injection as directed by your healthcare provider.**
 - 2. Report symptoms such as severe abdominal pain, swelling, or rapid weight gain immediately.**
 - 3. Attend all scheduled monitoring appointments to track follicular response and hormone levels.**
 - 4. Avoid self-administration unless trained by a healthcare professional.**
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Urofollitropin (75 IU) Injection is a reliable gonadotropin used to address infertility in women and men, helping improve outcomes in assisted reproductive technologies and hormonal therapies. Its use should always be guided by a fertility specialist to ensure safety and efficacy.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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Panchkula-134113

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