

Product name:	FOLIGRAF™ 150 I.U. Injection (Recombinant-Human Follicle Stimulating Hormone for Injection 150 I.U.) For subcutaneous usage
Read the instruction carefully before use: <ul style="list-style-type: none">• Keep this leaflet as you may need to read it again.• After reading if you have any further questions please ask your doctor.• This medicine has been prescribed for your symptoms.• If you notice any side effects or any disease as mentioned in this leaflet please tell your doctor or pharmacist.• Keep out of reach of children.	
What FOLIGRAF™ 150 I.U. is and what it is used for? <p>Foligraf™ 150 I.U. (r-hFSH*) is a preparation of follicle stimulating hormone produced by genetically engineered Chinese Hamster Ovary (CHO) cells. The dose of r-hFSH stimulates development of the follicle which must be individualized for each patient. It is a freeze dried powder accompanied by an ampoule containing 0.5 ml of sterilized Water for Injections for reconstitution.</p> <p>Foligraf™ 150 I.U. can be used in case of:</p> <ol style="list-style-type: none">1. Anovulation (including polycystic ovarian disease, PCOD) in women who have been unresponsive to treatment with clomiphene citrate.2. Stimulation of multifollicular development in patients undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilization (IVF), gamete intra-fallopian transfer (GIFT) and zygote intra-fallopian transfer (ZIFT).	
Before you take FOLIGRAF™ 150 I.U. <ul style="list-style-type: none">• Hypersensitivity to Foligraf™ 150 I.U. (r-hFSH), FSH or to any of the excipients• Case of tumors of the hypothalamus and pituitary gland• Ovarian enlargement or cyst not due to polycystic ovarian disease• Gynaecological haemorrhages of unknown aetiology• Ovarian, uterine or mammary carcinoma	
Take special care with FOLIGRAF™ 150 I.U. <p>Special population</p> <p><i>Older people</i></p> <p>There is no relevant use of r-hFSH in the elderly population. safety and effectiveness of r-hFSH in elderly patients have not been established.</p> <p><i>Renal or hepatic impairment</i></p> <p>Safety, efficacy and pharmacokinetics of r-hFSH in patients with renal or hepatic impairment have not been established.</p>	

Paediatric population

There is no relevant use of r-hFSH in the paediatric population.

FoligrafTM 150 I.U. should only be used by physicians who are thoroughly familiar with infertility problems and their management. Care should be taken to observe symptoms as given in warnings and adverse effects.

HOW TO TAKE FOLIGRAFTM 150 I.U.

Treatment with FoligrafTM 150 I.U. (r-hFSH) should be initiated under the supervision of a physician experienced in the treatment of fertility problems. FoligrafTM is given as an injection under the skin.

For anovulation, A commonly used regimen starts at 75-150 IU FSH daily and is increased preferably by 37.5 or 75 IU at 7 or preferably 14 day intervals if necessary, to obtain an adequate, but not excessive, response. The maximal daily dose is usually not higher than 225 IU FSH.

For ovarian stimulation, involves the administration of 150-225 IU of r-hFSH daily, commencing on days 2 or 3 of the cycle. Treatment is continued until adequate follicular development has been achieved with the dose adjusted according to your response, to usually not higher than 450 IU daily. In general adequate follicular development is achieved on average by the tenth day of treatment (range 5 to 20 days).

If you take more FOLIGRAFTM 150 I.U. than you should

OHSS can occur if dosage more than recommended has been used as described in undesirable effect.

If you forget to take FOLIGRAFTM 150 I.U.

Contact your doctor if you miss a dose of FoligrafTM 150 I.U.

POSSIBLE SIDE EFFECTS

FoligrafTM 150 I.U. should be used by Physicians who are thoroughly familiar with infertility & hormonal problems.

1. FoligrafTM 150 I.U. should be used only with appropriate monitoring facilities.
2. Lowest dose consistent with expectation of good result should be used.

It could cause:

- Very Common Symptoms: Ovarian cysts; Mild to severe injection site reaction (pain, redness, bruising, swelling and/or irritation at the site of injection); Headache.
- Common symptoms: Mild to moderate OHSS- Ovarian hyperstimulation syndrome which means ovarian overreacted to the medicine. Abdominal pain and gastrointestinal symptoms such as nausea, vomiting, diarrhoea, abdominal cramps and bloating.
- Uncommon symptoms: Severe OHSS
- Rare symptoms: Ovarian torsion, a complication of OHSS
- Very rare symptoms: Thromboembolism usually associated with severe OHSS; Mild systemic allergic reactions (erythema, rash or facial swelling).

HOW TO STORE FOLIGRAF™ 150 I.U.

Foligraf™ 150 I.U. should be stored under refrigeration at 2°C to 8°C. Foligraf™ 150 I.U. should not be frozen and should not be directly exposed to light. Keep it out of reach of children.

FURTHER INFORMATION

Ingredients, strength / concentration:

It contains 150 IU of r-hFSH

Description of finished product

Foligraf™ 150 I.U. (r-hFSH*) is a preparation of follicle stimulating hormone produced by genetically engineered Chinese Hamster Ovary (CHO) cells. The dose of r-hFSH stimulates development of the follicle which must be individualized for each patient. It is a freeze dried powder accompanied by an ampoule containing 0.5 ml of sterilized Water for Injections for reconstitution.

List of Excipients:

- Disodium hydrogen phosphate anhydrous B.P.
- Mannitol B.P.
- Sucrose B.P.
- Methionine B.P.
- Tween 20 (Polysorbate) B.P.
- Phosphoric acid, concentrated
- Sodium hydroxide
- Water for injections

Pack Size

Foligraf™ 150 I.U. is supplied in vial containing sterile, freeze dried white to off white powder having r-hFSH of 150 I.U.

Each vial is accompanied by an ampoule containing 0.5ml of Sterile Water for Injection.

Signs & Symptoms of overdose

The effects of an overdose of Foligraf™ 150 I.U. are unknown, nevertheless one could expect ovarian hyperstimulation syndrome to occur.

When should you consult your doctor, pharmacist?

When you experience any signs or symptoms as mentioned in adverse events you should immediately

Shelf-life of product

24 Months.



Patient Information Leaflet

The product license/ authorization holder is:

BHARAT SERUMS AND VACCINES LIMITED

Plot No. K-27, K-27 part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambarnath (East), Thane 421501 Maharashtra State, India.

Manufactured in India by:

BHARAT SERUMS AND VACCINES LIMITED

Plot No. K-27, K-27 part and K-27/1, Anand Nagar,
Jambivili Village, Additional MIDC, Ambarnath (East),
Thane 421501 Maharashtra State, India.

For any information about this medicinal product, please contact the <local representative of the> supplier:

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