Pack Insert
Date : 05APR24
Date : 22APR24*
Malaysia Export
(Ambernath)
(Revised)

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

Urofollitropin for Injection B.P.

Foliculin 75 I.U. / 150 I.U.

(Freeze Dried)

For Subcutaneous / Intramuscular Injection only

COMPOSITION:
Each vial contains :
Urofollitropin B.P. ..... 75 I.U. / 150 I.U.

Each vial of **Foliculin** is accompanied by an ampoule of Sodium Chloride Injection B.P. 1ml as solvent.

Product Description:
Before Reconstitution:
An almost white or slightly yellowish powder or cake.

After Reconstitution:
A clear colourless liquid.

Solvent Sodium Chloride Injection:
A clear and colourless solution.

Pharmacodynamics:
Foliculin 75 I.U. / 150 I.U. contains purified hormone urofollitropin, obtained from Human Menopausal urine having FSH activity of 75 I.U. / 150 I.U. and less than 1 IU/2 IU Luteinizing Hormone activity per vial Patients showing normal or high LH levels (WHO Group II) , require preparations without LH activity, this character belongs to FSH.
FSH stimulates both the growth and maturation of follicles, it induces secretion of oestrogens and proliferation of the endometrium.

ATC Code: G03GA04 - Urofollitropin.

Pharmacokinetics:
After multiple intramuscular dosing of Urofollitropin, the maximum plasma concentration of Follicle-stimulating hormone occurs about 10 hours after a dose, and has an elimination half-life of about 15 or 20 hours respectively.
Because there are no longer ovarian steroids and inhibin to inhibit LH and FSH secretion, gonadotropin secretion is greatly increased, and the levels of FSH are higher than those of LH in postmenopausal women.
FSH and LH are eliminated in two phases. In both phases the biological half-life of FSH is longer than that of LH.
The gonadotropins of either pituitary or placental origin are effective only if given by injection, usually intramuscularly. The rate at which gonadotropins are cleared from plasma is difficult to measure accurately because of their structural heterogeneity and the background of pulsatile secretion of the endogenous hormones.
The prolonged circulatory life of these glycoprotein hormone relative to many other peptide hormones is a result of their resistance to metabolic degradation in most tissue beds.
Clearance of injected (and presumably of endogenous) glycoprotein hormones is by glomerular filtration, followed by degradation in the proximal renal tubule or excretion (unchanged) in the urine. Removal of the sialic acid residues results in their rapid and complete clearance by the hepatic reticuloendothelial system.

INDICATIONS:
Foliculin is indicated for stimulation of follicular growth in infertile women. A course of **Foliculin** is usually followed by human chorionic gonadotrophin (HCG, Pubergen) to induce ovulation.

Foliculin is used :
a) For single follicular development in cases such as hypothalamic pituitary dysfunction (WHO Group II classification), include patients with polycystic ovarian disease.

b) For multiple follicular development (assisted conception techniques); in cases such as tubal occlusion, unexplained infertility and male factor infertility.

Recommended Dose:
The dose of **Foliculin** to produce maturation of follicle must be individualized for each patient.
It is recommended that initial dose to any patient should be 75 I.U. of **Foliculin** per day administered subcutaneous for at least 7 days followed by HCG 5000 I.U. to 10000 I.U. one day after last dose of **Foliculin**.
Courses of treatment should be no longer than 12 days.
If there is evidence of ovulation but no pregnancy, repeat above dosage regimen for at least 2 or more courses before increasing the dose to **Foliculin** 150 IU per day for 7-12 days. As stated above this dose should be followed by HCG 5000 I.U. to 10000 I.U. one day after last dose of **Foliculin**. If evidence of ovulation is present but pregnancy is not sure repeat the same dose for 2 more courses. Doses larger than this are not routinely recommended.

In-vitro Fertilization:
In-vitro fertilization therapy with **Foliculin** should be initiated in the early follicular phase (cycle day 2 or 3) at a dose of 150 I.U. per day until sufficient follicular development is attained. In most cases therapy should not exceed beyond 10 days.

Reconstitution Instructions:
Reconstitute the contents of vial containing **Foliculin** in 1ml of Sodium Chloride Injection BP and administer subcutaneous immediately.

Route of Administration:
Intramuscular (IM) + Subcutaneous (SC).

CONTRAINDICATION:
Foliculin is contraindicated in women who exhibit:
1. High levels of FSH, indicating primary ovarian failure.
2. Uncontrolled thyroid or adrenal dysfunction.
3. An organic intracranial lesion such as pituitary tumor.
4. The presence of any cause of infertility other than anovulation unless they are candidates for in vitro fertilization.
5. Ovarian cysts or enlargement not due to ovarian polycystic ovarian disease.
6. Prior hypersensitivity to Urofollitropin.
7. **Foliculin** is contraindicated in women who are pregnant. There are limited human data on the effects of **Foliculin** when administered during pregnancy.

Contraindicated for safety reasons in gynecological hemorrhages of unknown aetiology.

WARNINGS AND PRECAUTIONS:
Before starting treatment, the couple's infertility should be assessed as appropriate and putative contra-indications for pregnancy evaluated.
Adherence to the recommended dosage and monitoring schedules will minimize the possibility of ovarian hyperstimulation syndrome.
Excessive ovarian response to **Foliculin** treatment does generally not induce significant adverse effects except if hCG is administered for ovulation induction or if pregnancy occurs; ovarian hyper stimulation syndrome occurs usually 1 to 2 weeks following hCG administration and ovulation.
In case of symptoms such as pelvic pain, abdominal distension or ovarian enlargement or if oestrogen assays or ultrasound examinations suggest an excessive oestrogenic response, **Foliculin** administration should be discontinued and hCG should not be administered and intercourse avoided in order to prevent ovarian hyperstimulation.
Ascites, pericardial effusion, hydrothorax, hemo-concentration, secondary hyperaldosteronism or hypercoagulability might appear. These symptoms should be controlled through appropriate medical measure, including avoidance of unnecessary pelvic examination. In the absence of pregnancy, they usually resolve spontaneously with the onset of the menses.

Interactions with Other Medications:
No clinically significant adverse drug/drug or drug/food interactions have been reported during **Foliculin** therapy. Concomitant use of **Foliculin** and Clomifene citrate may potentiate the follicular response, whereas concurrent use of GnRH agonist induced pituitary desensitization may increase the dosage of **Foliculin** needed to elicit an adequate ovarian response.

PREGNANCY AND LACTATION:
Should not be given if pregnancy is suspected or to lactating mothers.

SIDE EFFECTS:
Local reactions at the injection site, fever and arthralgias have been reported following urofollitropins and Menotropins administration.
Gastrointestinal symptoms may occur as well as bloating of the stomach, pelvic pain or sore breasts. Mild to moderate ovarian enlargement, ovarian cysts may be observed. Severe hyper stimulation syndrome is rare. In rare instances, arterial thromboembolisms have been associated with menotropin human chorionic gonadotrophin therapy.
Pregnancy wastage by miscarriage or abortion is comparable with the rates in women with other fertility problems. Ectopic pregnancy may occur in women with a history of prior tubal disease.

Symptoms and Treatment of Overdose:
There are no reports of toxic effects occurring as a result of overdosage. However, an ovarian hyperstimulation syndrome cannot be ruled out. Aside from possible ovarian overstimulation and multiple gestations, little is known concerning the consequence of acute overdosage with **Foliculin.**

EFFECTS ON ABILITY TO DRIVE AND USE MACHINE:
No studies on the effects on the ability to drive and use machines have been performed. However, **Foliculin** is unlikely to have influence on the patient's performance to drive and use machines.

STORAGE CONDITION:
Vials of **Foliculin** with 1ml Sodium Chloride Injection BP as solvent should be stored between 2°C-8°C. Do not freeze. Protect from light.
Reconstituted solution of **Foliculin** should be used immediately after preparation. Discard any unused portion.

SHELF LIFE:
Foliculin Injection: 36 months.
Solvent Sodium Chloride Injection: 60 months.

PRESENTATION:
Foliculin Injection 75 I.U. (Urofollitropin for injection BP-Freeze Dried) is supplied in vial containing sterile, freeze dried almost white or slightly yellowish powder or cake having FSH activity of 75 I.U. Each vial is accompanied by an ampoule with the protective sleeve containing 1 ml of sodium chloride Injection B.P. as diluent in a carton along with pack insert and an ampoule breaking manual.
Foliculin Injection 150 I.U. (Urofollitropin for injection BP-Freeze Dried) is supplied in vial containing sterile, freeze dried almost white or slightly yellowish powder or cake having FSH activity of 150 I.U. Each vial is accompanied by an ampoule with the protective sleeve containing 1 ml of sodium chloride Injection B.P. as diluent in a carton along with pack insert and an ampoule breaking manual.

REVISION DATE : April 2024

Manufactured by :
BSV **BHARAT SERUMS AND VACCINES LIMITED**
Plot No. K-27, K-27 Part and K-27/1, Anand Nagar, Jambivili Village, Additional MIDC, Ambernath (East), Thane 421506, Maharashtra State, India.

Product Registration Holder :
BSV BioScience Malaysia Sdn. Bhd.
No.3, JLN 19/1, 46300, P.J, Selangor, Malaysia.

IN90047E4MY

New Size : L x H = 107.5 x 145 mm.

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Pantone Process Black C | **50% Pantone Process Black C** | **40% Pantone Process Black C** | **20% Pantone Process Black C**

Paper : 40 gsm, ITC Print Paper
Outline & Cutting marks not to print
Artwork Code No. : IN90047E4MY
Back to Back Printing
2 Horizontal Folds