1. **FOLICULIN™** should be used only with appropriate monitoring facilities.
2. Lowest dose consistent with expectation of good result should be used.

Ovarian response should be carefully monitored to minimize the risk of over stimulation.

If the ovaries are abnormally enlarged on last day of **FOLICULIN™** therapy, HCG should not to be administered in this course therapy. This reduces development of OHSS (Ovarian Hyperstimulation Syndrome).

Dosage and Administration :

Dosage :

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 intramuscularly for 7-12 days followed by HCG 5000 I.U. to 10000 I.U. one day after last dose of **FOLICULIN™**.

Administration of **FOLICULIN™** may exceed 12 days if inadequate Follicle development is indicated by oestrogen and / or ultrasound measurements.

If there is evidence of ovulation but no pregnancy, repeat above dosage regimen for atleast 2 or more courses before increasing the dose to **FOLICULIN™** 150 I.U. 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.

Administration :

Reconstitute the contents of vial containing **FOLICULIN™** in 1ml of Sodium Chloride Injection and administer intramuscularly immediately. Any unused portion of reconstituted solution should be discarded.

Storage :

Vials of **FOLICULIN™** should be stored between $2^{\circ}C$ - $8^{\circ}C$. Do not freeze. Protect from light.

Reconstituted solution of **FOLICULIN™** should be used immediately after preparation. Discard any unused portion.

Presentation :

FOLICULIN™ is supplied in vial containing sterile, freeze dried white to off white powder having FSH activity of 75 I.U. / 150 I.U. Each vial is accompanied by an ampoule containing 1ml of Sodium Chloride Injection I.P.

Manufactured in India by :
BHARAT SERUMS AND VACCINES LIMITED
Plot No. K-27, Additional M.I.D.C., Ambernath (E) - 421 501

IN90047D3

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

Urofollitropin For Injection B.P. (FSH)

फॉलिक्युलिन

FOLICULIN® **75 / 150**

75 I.U. / 150 I.U.

(Freeze Dried)

For Intramuscular Injection only

Composition :

Each vial contains :

Urofollitropin B.P. equivalent to activity of Follicle Stimulating Hormone ..... 75 I.U. / 150 I.U.

Each vial of **FOLICULIN™** (FSH) is accompanied by an ampoule containing 1ml of Sodium Chloride Injection I.P.

Properties :

FOLICULIN™ contains a purified hormone urofollitropin, obtained from Human Menopausal urine having FSH activity of 75 I.U. / 150 I.U. and less than 1 I.U. / 2 I.U. Luteinizing Hormone activity per vial. Human menopausal gonadotrophins (HMG) exerts both FSH and LH activities. For this reason, HMG is indicated in Hypogonadotropic hypopituitarism (WHO Group I patients), where both gonadotrophin stimulations are needed.

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.

Indications :

FOLICULIN™ and Human Chorionic Gonadotropin (HCG) given in a sequential manner are indicated for induction of ovulation in patients with Polycystic Ovarian Disease (PCOD) who have an elevated LH / FSH ratio and who have failed to respond to adequate clomiphene citrate therepy.

FOLICULIN™ and HCG may also be used to stimulate the development of multiple oocytes in ovulatory patients participating in an in vivo fertility program.

Contra-indications :

FOLICULIN™ is contra-indicated in women who exhibit :

1. High levels of FSH, indicating primary ovarian failure.
2. Uncontrolled thyroid or adrental 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 vitrofertilization.
5. Ovarian cysts or enlargement not due to ovarian polycystic Ovarian Disease.
6. Prior hypersensitivity to Urofolltropin.
7. **FOLICULIN™** is contra-indicated in women who are pregnant. There are limited human data on the effects of **FOLICULIN™** when administered during pregnancy.

Warning :

FOLICULIN™ should be used by Physicians who are thoroughly familiar with infertility problems.