5.5 mcg
GONAL-f® contains a hormone that is called the follicle-stimulating hormone, which is abbreviated to FSH. It is produced by genetic engineering.

**Composition**
The active substance is follitropin alfa. Follitropin alfa is a recombinant human follicle stimulating hormone (FSH) produced by recombinant DNA technology in Chinese Hamster Ovary (CHO) cell line, belonging to the pharmacotherapeutic cell line, belonging to the pharmacotherapeutic cell line.

GONAL-f® 75 IU (5.5 micrograms) is injected under the skin (subcutaneously). The powder (which contains the active substance) must be dissolved with the solvent contained in the ready-to-use syringe and the injection must be carried out immediately after preparation of the solution.

**Indications**
- GONAL-f can be used to cause ovulation in women who are not ovulating and who have not responded to treatment with clomiphene citrate.
- GONAL-f is used to bring about the development of several follicles (and therefore several eggs) for women undergoing assisted reproductive technologies such as *in vitro* fertilisation, gamete intra-fallopian transfer or zygote intra-fallopian transfer.
- GONAL-f is used together with another hormone called lutropin alfa (recombinant human luteinising hormone) to cause ovulation in women who are not ovulating due to very low production of the fertility hormones (FSH and LH) by their pituitary gland.
- GONAL-f is used in combination with another medicine, human chorionic gonadotrophin (hCG), to produce sperm in men who are infertile due to hormonal deficiency infertile due to hormonal deficiency.
- GONAL-f is used in combination with another medicine, human chorionic gonadotrophin (hCG), to produce sperm in men who are infertile due to hormonal deficiency.

**Contraindication**
- hypersensitivity to follicle stimulating hormone or to any of the other ingredients of GONAL-f
- tumours of the hypothalamus and pituitary gland
- ovarian enlargement or cyst not due to polycystic ovarian disease
- gynaecological bleeding of unknown cause
- ovarian, uterine or breast cancer
- if you have irreversible testicular damage.

The medicine should not be used when a condition exists which would make a normal pregnancy impossible, such as premature menopause malformation of sexual organs or specific tumours of the womb.

**Dosage & administration**
GONAL-f is administered by injection just under the skin (subcutaneous use). Women who are not ovulating and are having irregular periods or no periods at all.

GONAL-f is usually given every day. The treatment should start within the first 7 days of the menstrual cycle.

A commonly used dose starts at 75-150 IU FSH every day (0.12-0.24 ml). This maybe increased by 37.5-75 IU at 7 or preferably 14 but not excessive, response. The maximal daily dose is usually lower than 225 IU FSH (0.36 ml). If your doctor cannot see a response after 4 weeks of treatment, that treatment cycle should be abandoned. For the following cycle, your doctor will prescribe a treatment at a higher starting dose than in the abandoned cycle.

When an optimal response is obtained, a single injection of another medicine (hCG) is administered 24-48 hours after the last GONAL-f injection. You are recommended to have sexual intercourse on the day of the administration of this second medicine and the following day. If an excessive response is obtained, treatment should be stopped and hCG withheld (see Possible side effects). For the following cycle, your doctor will prescribe a dosage lower than that of the previous cycle. Women undergoing ovarian stimulation for multiple follicular development.
prior to *in vitro* fertilisation or other assisted reproductive technologies A commonly used dose for superovulation involves the administration of 150-225 IU (0.24-0.36 ml) of GONAL-f daily, commencing on days 2 or 3 of the treatment cycle.

Treatment is continued until adequate follicular development has been achieved (as assessed by blood monitoring and/or ultrasound examination) with the dose adjusted according to your response, to usually not higher than 450 IU (0.72 ml) daily. Adequate follicular development is usually achieved on average by the tenth day of treatment (range 5 to 20 days). Then a single injection of a medicine used to induce final follicular maturation and containing 250 micrograms r-hCG or 5000 IU up to 10 000 IU human chorionic gonadotrophin (hCG) is administered 24-48 hours after the last GONAL-f injection. Women who are not ovulating, having no periods at all and have been diagnosed as FSH and LH deficient.

GONAL-f is usually taken every day for up to five weeks simultaneously with injections of lutropin alfa. A commonly used dose starts with 75-150 IU (0.12-0.24 ml) of GONAL-f together with 75 IU of lutropin alfa.

According to your response, your doctor may increase your dose of GONAL-f by preferably 37.5-75 IU at 7 to 14-day intervals. If your doctor does not observe a response of your ovaries after 5 weeks of treatment, that cycle should be abandoned. For the following cycle, your doctor may prescribe treatment at a higher starting dose of GONAL-f than in the abandoned cycle. When the desired response has been obtained, a single injection of 250 micrograms r-hCG or 5000 IU up to 10 000 IU hCG is given 24-48 hours after the last injections of GONAL-f and lutropin alfa. Infertile men with hormonal deficiency GONAL-f is usually prescribed at a dose of 150 IU (0.24 ml) three times a week in combination with another medicine (hCG) for at least 4 months. If you have not responded to treatment after this period, your treatment may carry on for at least 18 months.

**Possible side effects**
The most commonly reported side effects are ovarian cysts, headache and local reactions at the injection site (pain, redness, bruising, swelling and/or irritation).

Following treatment with GONAL-f when human chorionic gonadotrophin is administered a condition called ovarian hyper stimulation syndrome. This syndrome is characterized by large ovarian cysts. First symptoms of ovarian hyperstimulation are pain in the lower abdomen, nausea, vomiting and weight gain.

Isolated cases of non-serious allergic reactions to GONAL-f have been reported. This occurs in less than 1 patient for each 10 000 treated. Ectopic pregnancy (embryo implanted outside the womb) may occur especially in women with a history of pelvic disease.

Men may experience some breast development, acne or weight gain due to treatment with hCG (between 1 and 10% of the patients).

**Stability And Storage**
Store at 2°C-8°C (in a refrigerator). Do not freeze.

Within its shelf-life.