GONAL-f® PRE-FILLED PEN
Follitropin alfa

1. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each mL of the solution contains 600 IU of follitropin alfa*, (equivalent to 44 micrograms).

GONAL-f 150 IU/0.24 mL: Each pre-filled multidose pen delivers 150 IU (equivalent to 11 micrograms) in 0.24 mL.

GONAL-f 300 IU/0.48 mL: Each pre-filled multidose pen delivers 300 IU (equivalent to 22 micrograms) in 0.48 mL.

GONAL-f 900 IU/1.44 mL: Each pre-filled multidose pen delivers 900 IU (equivalent to 66 micrograms) in 1.44 mL.

* recombinant human follicle stimulating hormone (r-hFSH) produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology.

For the full list of excipients, see section 5.1 List of excipients.

2. PHARMACEUTICAL FORM
Solution for injection in a pre-filled pen.

Clear colourless solution.

3. CLINICAL PARTICULARS
3.1 Therapeutic indications
In adult women
- Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomiphene citrate.
- Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as *in vitro* fertilisation (IVF), gamete intra-fallopian transfer and zygote intra-fallopian transfer.
- GONAL-f in association with a luteinising hormone (LH) preparation is recommended for the stimulation of follicular development in women with severe LH and FSH deficiency. In clinical trials these patients were defined by an endogenous serum LH level < 1.2 IU/L.

In adult men
- GONAL-f is indicated for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotrophic hypogonadism with concomitant human Chorionic Gonadotropin (hCG) therapy.

3.2 Posology and method of administration
Treatment with GONAL-f should be initiated under the supervision of a physician experienced in the treatment of fertility disorders.

Patients must be provided with the correct number of pens for their treatment course and educated to use the proper injection techniques.

Posology
The dose recommendations given for GONAL-f are those in use for urinary FSH. Clinical assessment of GONAL-f indicates that its daily doses, regimens of administration, and treatment monitoring procedures should not be different from those currently used for urinary FSH-containing medicinal products. It is advised to adhere to the recommended starting doses indicated below.

Comparative clinical studies have shown that on average patients require a lower cumulative dose and shorter treatment duration with GONAL-f compared with urinary FSH. Therefore, it is considered appropriate to give a lower total dose of GONAL-f than generally used for urinary FSH, not only in order to optimise follicular development but also to minimise the risk of unwanted ovarian hyperstimulation (*see section 4.1 Pharmacodynamic properties*).

Bioequivalence has been demonstrated between equivalent doses of the monodose presentation and the multidose presentation of GONAL-f.

Women with anovulation (including polycystic ovarian syndrome)

GONAL-f may be given as a course of daily injections. In menstruating women treatment should commence within the first 7 days of the menstrual cycle.

A commonly used regimen commences 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. Treatment should be tailored to the individual patient's response as assessed by measuring follicle size by ultrasound and/or oestrogen secretion. The maximal daily dose is usually not higher than 225 IU FSH. If a patient fails to respond adequately after 4 weeks of treatment, that cycle should be abandoned, and the patient should undergo further evaluation after which she may recommence treatment at a higher starting dose than in the abandoned cycle.

When an optimal response is obtained, a single injection of 250 micrograms recombinant human choriogonadotropin alfa (r-hCG) or 5,000 IU, up to 10,000 IU hCG should be administered 24-48 hours after the last GONAL-f injection. The patient is recommended to have coitus on the day of, and the day following, hCG administration. Alternatively, intrauterine insemination (IUI) may be performed.

If an excessive response is obtained, treatment should be stopped and hCG withheld (*see section 3.4 Special warnings and precautions for use*). Treatment should recommence in the next cycle at a dose 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 regimen for superovulation involves the administration of 150-225 IU of GONAL-f daily, commencing on days 2 or 3 of the cycle. Treatment is continued until adequate follicular development has been achieved (as assessed by monitoring of serum oestrogen concentrations and/or ultrasound examination), with the dose adjusted according to the patient's 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).

A single injection of 250 micrograms r-hCG or 5,000 IU up to 10,000 IU hCG is administered 24-48 hours after the last GONAL-f injection to induce final follicular maturation.

Down-regulation with a gonadotropin-releasing hormone (GnRH) agonist or antagonist is now commonly used in order to suppress the endogenous LH surge and to control tonic levels of LH. In a commonly used protocol, GONAL-f is started approximately 2 weeks after the start of agonist treatment, both being continued until adequate follicular development is achieved. For example, following two weeks of treatment with an agonist, 150-225 IU GONAL-f are administered for the first 7 days. The dose is then adjusted according to the ovarian response.

Overall experience with IVF indicates that in general the treatment success rate remains stable during the first four attempts and gradually declines thereafter.

Women with anovulation resulting from severe LH and FSH deficiency
In LH and FSH deficient women (hypogonadotrophic hypogonadism), the objective of GONAL-f therapy in association with lutropin alfa is to develop a single mature Graafian follicle from which the oocyte will be liberated after the administration of human chorionic gonadotropin (hCG). GONAL-f should be given as a course of daily injections simultaneously with lutropin alfa. Since these patients are amenorrhoeic and have low endogenous oestrogen secretion, treatment can commence at any time.

A recommended regimen commences at 75 IU of lutropin alfa daily with 75-150 IU FSH. Treatment should be tailored to the individual patient's response as assessed by measuring follicle size by ultrasound and oestrogen response.

If an FSH dose increase is deemed appropriate, dose adaptation should preferably be after 7-14 day intervals and preferably by 37.5-75 IU increments. It may be acceptable to extend the duration of stimulation in any one cycle to up to 5 weeks.

When an optimal response is obtained, a single injection of 250 micrograms r-hCG or 5,000 IU up to 10,000 IU hCG should be administered 24-48 hours after the last GONAL-f and lutropin alfa injections. The patient is recommended to have coitus on the day of, and on the day following, hCG administration. Alternatively, IUI may be performed.

Luteal phase support may be considered since lack of substances with luteotrophic activity (LH/hCG) after ovulation may lead to premature failure of the corpus luteum.

If an excessive response is obtained, treatment should be stopped and hCG withheld. Treatment should recommence in the next cycle at a dose of FSH lower than that of the previous cycle.

Men with hypogonadotrophic hypogonadism
GONAL-f should be given at a dose of 150 IU three times a week, concomitantly with hCG, for a minimum of 4 months. If after this period, the patient has not responded, the combination treatment may be continued; current clinical experience indicates that treatment for at least 18 months may be necessary to achieve spermatogenesis.

Special populations
Elderly population
There is no relevant use of GONAL-f in the elderly population. Safety and effectiveness of GONAL-f in elderly patients have not been established.

Renal or hepatic impairment
Safety, efficacy and pharmacokinetics of GONAL-f in patients with renal or hepatic impairment have not been established.

Paediatric population
There is no relevant use of GONAL-f in the paediatric population.

Method of administration
GONAL-f is intended for subcutaneous administration. The injection should be given at the same time each day.

The first injection of GONAL-f should be performed under direct medical supervision. Self-administration of GONAL-f should only be performed by patients who are well motivated, adequately trained and have access to expert advice.

As GONAL-f pre-filled pen with multidose cartridge is intended for several injections, clear instructions should be provided to the patients to avoid misuse of the multidose presentation.

3.3 Contraindications
- Hypersensitivity to follitropin alfa or to any of the excipients listed in section 5.1 List of excipients
- Tumours of the hypothalamus or pituitary gland
- Ovarian enlargement or ovarian cyst not due to polycystic ovarian syndrome
- Gynaecological haemorrhages of unknown aetiology
- Ovarian, uterine or mammary carcinoma

GONAL-f must not be used when an effective response cannot be obtained, such as:
- Primary ovarian failure
- Malformations of sexual organs incompatible with pregnancy
- Fibroid tumours of the uterus incompatible with pregnancy
- Primary testicular insufficiency

3.4 Special warnings and precautions for use
General recommendations
GONAL-f is a potent gonadotrophic substance capable of causing mild to severe adverse reactions and should only be used by physicians who are thoroughly familiar with infertility problems and their management.

Gonadotropin therapy requires a certain time commitment by physicians and supportive health professionals, as well as the availability of appropriate monitoring facilities. In women, safe and effective use of GONAL-f calls for monitoring of ovarian response with ultrasound, alone or preferably in combination with measurement of serum oestradiol levels, on a regular basis. There may be a degree of interpatient variability in response to FSH administration, with a poor response to FSH in some patients and exaggerated response in others. The lowest effective dose in relation to the treatment objective should be used in both men and women.

Porphyria
Patients with porphyria or a family history of porphyria should be closely monitored during treatment with GONAL-f. Deterioration or a first appearance of this condition may require cessation of treatment.

Treatment in women
Before starting treatment, the couple's infertility should be assessed as appropriate and putative contraindications for pregnancy evaluated. In particular, patients should be evaluated for hypothyroidism, adrenocortical deficiency, hyperprolactinemia and appropriate specific treatment given.

Patients undergoing stimulation of follicular growth, whether as treatment for anovulatory infertility or ART procedures, may experience ovarian enlargement or develop hyperstimulation. Adherence to recommended GONAL-f dose and regimen of administration, and careful monitoring of therapy will minimise the incidence of

such events. For accurate interpretation of the indices of follicle development and maturation, the physician should be experienced in the interpretation of the relevant tests.

In clinical trials, an increase of the ovarian sensitivity to GONAL-f was shown when administered with lutropin alfa. If an FSH dose increase is deemed appropriate, dose adaptation should preferably be at 7-14 day intervals and preferably with 37.5-75 IU increments.

No direct comparison of GONAL-f/LH versus human menopausal gonadotropin (hMG) has been performed. Comparison with historical data suggests that the ovulation rate obtained with GONAL-f/LH is similar to that obtained with hMG.

Ovarian Hyperstimulation Syndrome (OHSS)
A certain degree of ovarian enlargement is an expected effect of controlled ovarian stimulation. It is more commonly seen in women with polycystic ovarian syndrome and usually regresses without treatment.

In distinction to uncomplicated ovarian enlargement, OHSS is a condition that can manifest itself with increasing degrees of severity. It comprises marked ovarian enlargement, high serum sex steroids, and an increase in vascular permeability which can result in an accumulation of fluid in the peritoneal, pleural and, rarely, in the pericardial cavities.

The following symptomatology may be observed in severe cases of OHSS: abdominal pain, abdominal distension, severe ovarian enlargement, weight gain, dyspnoea, oliguria and gastrointestinal symptoms including nausea, vomiting and diarrhoea. Clinical evaluation may reveal hypovolaemia, haemoconcentration, electrolyte imbalances, ascites, haemoperitoneum, pleural effusions, hydrothorax, or acute pulmonary distress. Very rarely, severe OHSS may be complicated by ovarian torsion or thromboembolic events such as pulmonary embolism, ischaemic stroke or myocardial infarction.

Independent risk factors for developing OHSS include polycystic ovarian syndrome high absolute or rapidly rising serum oestradiol levels (e.g. > 900 pg/mL or > 3,300 pmol/L in anovulation; > 3,000 pg/mL or > 11,000 pmol/L in ART) and large number of developing ovarian follicles (e.g. > 3 follicles of ≥ 14 mm in diameter in anovulation; ≥ 20 follicles of ≥ 12 mm in diameter in ART).

Adherence to recommended GONAL-f dose and regimen of administration can minimise the risk of ovarian hyperstimulation (*see section 3.2 Posology and method of administration and section 3.8 Undesirable effects*). Monitoring of stimulation cycles by ultrasound scans as well as oestradiol measurements are recommended to early identify risk factors.

There is evidence to suggest that hCG plays a key role in triggering OHSS and that the syndrome may be more severe and more protracted if pregnancy occurs. Therefore, if signs of ovarian hyperstimulation occur such as serum oestradiol level > 5,500 pg/mL or > 20,200 pmol/L and/or ≥ 40 follicles in total, it is recommended that hCG be withheld and the patient be advised to refrain from coitus or to use barrier contraceptive methods for at least 4 days. OHSS may progress rapidly (within 24 hours) or over several days to become a serious medical event. It most often occurs after hormonal treatment has been discontinued and reaches its maximum at about seven to ten days following treatment. Therefore, patients should be followed for at least two weeks after hCG administration.

In ART, aspiration of all follicles prior to ovulation may reduce the occurrence of hyperstimulation.

Mild or moderate OHSS usually resolves spontaneously. If severe OHSS occurs, it is recommended that gonadotropin treatment be stopped if still ongoing, and that the patient be hospitalised and appropriate therapy be started.

Multiple pregnancy
In patients undergoing ovulation induction, the incidence of multiple pregnancy is increased compared with natural conception. The majority of multiple conceptions are twins. Multiple pregnancy, especially of high order, carries an increased risk of adverse maternal and perinatal outcomes.

To minimise the risk of multiple pregnancy, careful monitoring of ovarian response is recommended.

In patients undergoing ART procedures the risk of multiple pregnancy is related mainly to the number of embryos replaced, their quality and the patient age.

The patients should be advised of the potential risk of multiple births before starting treatment.

Pregnancy loss
The incidence of pregnancy loss by miscarriage or abortion is higher in patients undergoing stimulation of follicular growth for ovulation induction or ART than following natural conception.

Ectopic pregnancy
Women with a history of tubal disease are at risk of ectopic pregnancy, whether the pregnancy is obtained by spontaneous conception or with fertility treatments. The prevalence of ectopic pregnancy after ART, was reported to be higher than in the general population.

Reproductive system neoplasms
There have been reports of ovarian and other reproductive system neoplasms, both benign and malignant, in women who have undergone multiple treatment regimens for infertility treatment. It is not yet established whether or not treatment with gonadotropins increases the risk of these tumours in infertile women.

Congenital malformation
The prevalence of congenital malformations after ART may be slightly higher than after spontaneous conceptions. This is thought to be due to differences in parental characteristics (e.g. maternal age, sperm characteristics) and multiple pregnancies.

Thromboembolic events
In women with recent or ongoing thromboembolic disease or women with generally recognised risk factors for thrombo-embolic events, such as personal or family history, treatment with gonadotropins may further increase the risk for aggravation or occurrence of such events. In these women, the benefits of gonadotropin administration need to be weighed against the risks. It should be noted however that pregnancy itself as well as OHSS also carry an increased risk of thrombo-embolic events.

Treatment in men
Elevated endogenous FSH levels are indicative of primary testicular failure. Such patients are unresponsive to GONAL-f/hCG therapy. GONAL-f should not be used when an effective response cannot be obtained.

Semen analysis is recommended 4 to 6 months after the beginning of treatment as part of the assessment of the response.

Sodium content
GONAL-f contains less than 1 mmol sodium (23 mg) per dose, i.e. it is essentially “sodium-free”.

3.5 Interaction with other medicinal products and other forms of interaction
Applies only to single use presentation forms
GONAL-f must not be administered as a mixture with other medicinal products in the same injection, except lutropin alfa or combination of lutropin alfa and follitropin alfa for which studies have shown that co-administration dose not significantly alter the activity, stability, pharmacokinetics nor pharmacodynamic properties of the active substances.

Applies to all presentation forms
Concomitant use of GONAL-f with other medicinal products used to stimulate ovulation (e.g. hCG, clomiphene citrate) may potentiate the follicular response, whereas concurrent use of a GnRH agonist or antagonist to induce pituitary desensitisation may increase the dose of GONAL-f needed to elicit an adequate ovarian response. No other clinically significant medicinal product interaction has been reported during GONAL-f therapy.

3.6 Fertility, pregnancy and lactation
Pregnancy
There is no indication for use of GONAL-f during pregnancy. Data on a limited number of exposed pregnancies (less than 300 pregnancy outcomes) indicate no malformative or feto/neonatal toxicity of follitropin alfa.

No teratogenic effect has been observed in animal studies (*see section 4.3 Preclinical safety data*).

In case of exposure during pregnancy, clinical data are not sufficient to exclude a teratogenic effect of GONAL-f.

Breastfeeding
GONAL-f is not indicated during breastfeeding. During lactation, the secretion of prolactin can result in a poor prognosis to ovarian stimulation.

3.7 Effects on ability to drive and use machines
GONAL-f is expected to have no or negligible influence on the ability to drive and use machines.

3.8 Undesirable effects
Summary of the safety profile

The most commonly reported adverse reactions are headache, ovarian cysts and local injection site reactions (e.g. pain, erythema, haematoma, swelling and/or irritation at the site of injection).

Mild or moderate ovarian hyperstimulation syndrome (OHSS) have been commonly reported and should be considered as an intrinsic risk of the stimulation procedure. Severe OHSS is uncommon (*see section 3.4 Special warnings and precautions for use*).

Thromboembolism may occur very rarely (*see section 3.4 Special warnings and precautions for use*).

List of adverse reactions
The following definitions apply to the frequency terminology used hereafter:
Very common (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to < 1/1,000)
Very rare (< 1/10,000)

Treatment in general
Immune system disorders
Very rare: Mild to severe hypersensitivity reactions including anaphylactic reactions and shock

Respiratory, thoracic, and mediastinal disorders
Very rare: Exacerbation or aggravation of asthma

General disorders and administration site conditions
Very common: Injection site reactions (e.g. pain, erythema, haematoma, swelling and/or irritation at the site of injection)

Treatment in women
Nervous system disorders
Very common: Headache

Vascular disorders
Very rare: Thromboembolism (both in association with and separate from OHSS) (*see section 3.4 Special warnings and precautions for use).*

Gastrointestinal disorders
Common: Abdominal pain, abdominal distension, abdominal discomfort, nausea, vomiting, diarrhoea

Reproductive system and breast disorders
Very common : Ovarian cysts
Common: Mild or moderate OHSS (including associated symptomatology)
Uncommon: Severe OHSS (including associated symptomatology) (*see section 3.4 Special warnings and precautions for use*).
Rare: Complication of severe OHSS

Treatment in men
Skin and subcutaneous tissue disorders
Common: Acne

Reproductive system and breast disorders
Common: Gynaecomastia, Varicocele

Investigations
Common: Weight gain

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.

3.9 Overdose
The effects of an overdose of GONAL-f are unknown, nevertheless, there is a possibility that OHSS may occur (*see section 4.4 Special warnings and precautions for use*).

4. PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sex hormones and modulators of the genital systems, gonadotropins, ATC code: G03GA05.

In women, the most important effect resulting from parenteral administration of FSH is the development of mature Graafian follicles. In women with anovulation, the object of GONAL-f therapy is to develop a single mature Graafian follicle from which the ovum will be liberated after the administration of hCG.

Clinical efficacy and safety in women

In clinical trials, patients with severe FSH and LH deficiency were defined by an endogenous serum LH level < 1.2 IU/L as measured in a central laboratory. However, it should be taken into account that there are variations between LH measurements performed in different laboratories.

In clinical studies comparing r-hFSH (follitropin alfa) and urinary FSH in ART (*see table below*) and in ovulation induction, GONAL-f was more potent than urinary FSH in terms of a lower total dose and a shorter treatment period needed to trigger follicular maturation.

In ART, GONAL-f at a lower total dose and shorter treatment period than urinary FSH, resulted in a higher number of oocytes retrieved when compared to urinary FSH.

Table: Results of study GF 8407 (randomised parallel group study comparing efficacy and safety of GONAL-f with urinary FSH in assisted reproduction technologies)

	GONAL-f (n = 130)	**urinary FSH (n = 116)**
Number of oocytes retrieved	11.0 ± 5.9	8.8 ± 4.8
Days of FSH stimulation required	11.7 ± 1.9	14.5 ± 3.3
Total dose of FSH required (number of FSH 75 IU ampoules)	27.6 ± 10.2	40.7 ± 13.6
Need to increase the dose (%)	56.2	85.3

Differences between the 2 groups were statistically significant ($p < 0.05$) for all criteria listed.

Clinical efficacy and safety in men

In men deficient in FSH, GONAL-f administered concomitantly with hCG for at least 4 months induces spermatogenesis.

4.2 Pharmacokinetic properties

Following intravenous administration, follitropin alfa is distributed to the extracellular fluid space with an initial half-life of around 2 hours and eliminated from the body with a terminal half-life of about one day. The steady state volume of distribution and total clearance are 10 L and 0.6 L/h, respectively. One-eighth of the follitropin alfa dose is excreted in the urine.

Following subcutaneous administration, the absolute bioavailability is about 70%. Following repeated administration, follitropin alfa accumulates 3-fold achieving a steady-state within 3-4 days. In women whose endogenous gonadotropin secretion is suppressed, follitropin alfa has nevertheless been shown to effectively stimulate follicular development and steroidogenesis, despite unmeasurable LH levels.

Pharmacokinetics in special populations

The pharmacokinetic data obtained from the Japanese studies were similar to those observed in the phase I studies performed with Caucasians.

4.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of single and repeated dose toxicity and genotoxicity additional to that already stated in other sections of this product information.

Impaired fertility has been reported in rats exposed to pharmacological doses of follitropin alfa (≥ 40 IU/kg/day) for extended periods, through reduced fecundity.

Given in high doses (≥ 5 IU/kg/day) follitropin alfa caused a decrease in the number of viable foetuses without being a teratogen, and dystocia similar to that observed with urinary Menopausal Gonadotropin (hMG). However, since GONAL-f is not indicated in pregnancy, these data are of limited clinical relevance.

5. PHARMACEUTICAL PARTICULARS

5.1 List of excipients

Poloxamer 188
Sucrose
Methionine

Sodium dihydrogen phosphate monohydrate
Disodium phosphate dihydrate
m-Cresol
Phosphoric acid, concentrated
Sodium hydroxide
Water for injections

5.2 Incompatibilities
Not applicable.

5.3 Shelf-life
The expiry date is indicated on the packaging.

5.4 Special precautions for storage
Store in a refrigerator (2°C-8°C). Do not freeze.

Before opening and within its shelf life, the medicinal product may be stored outside of the refrigerator at temperatures up to a maximum of 25°C for a single period of up to 3 months. The product must be discarded if it has not been used within these 3 months.

Keep the cap on the pen in order to protect from light.

Once opened, the medicinal product should be stored between 2°C and 25°C for a maximum of 28 days. The patient should write on the GONAL-f pre-filled pen the day of the first use.

5.5 Nature and contents of container
GONAL-f 150 IU/0.24 mL
0.24 mL of solution for injection in 3 mL cartridge (Type I glass), with a plunger stopper (halobutyl rubber) and an aluminium crimp cap with a black rubber inlay.

Pack of one pre-filled pen and 4 needles to be used with the pen for administration.

GONAL-f 300 IU/0.48 mL
0.48 mL of solution for injection in 3 mL cartridge (Type I glass), with a plunger stopper (halobutyl rubber) and an aluminium crimp cap with a black rubber inlay.

Pack of one pre-filled pen and 8 needles to be used with the pen for administration.

GONAL-f 900 IU/1.44 mL
1.44 mL of solution for injection in 3 mL cartridge (Type I glass), with a plunger stopper (halobutyl rubber) and an aluminium crimp cap with a black rubber inlay.

Pack of one pre-filled pen and 20 needles to be used with the pen for administration.

5.6 Special precautions for disposal and other handling
The solution should not be administered if it contains particles or is not clear.

Any unused solution must be discarded not later than 28 days after first opening.

GONAL-f 150 IU/0.24 mL solution for injection in pre-filled pen, GONAL-f 300 IU/0.48 mL solution for injection in pre-filled pen, and GONAL-f 900 IU/1.44 mL solution for injection in pre-filled pen are not designed to allow the cartridge to be removed.

Discard used needles immediately after injection.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6. MANUFACTURER(S)
Manufactured by Merck Serono S.p.A., Bari, Italy
Imported by PT Merck Tbk, Jakarta, Indonesia

7. MARKETING AUTHORISATION HOLDER
Registered by PT Merck Tbk, Jakarta, Indonesia

8. PACKAGE QUANTITIES AND REGISTRATION NUMBER
GONAL-f 150 IU/0.24 mL: Box, 1 cartridge in a pre-filled pen + 4 needles Reg. No. DKI0980501043A1
GONAL-f 300 IU/0.48 mL: Box, 1 cartridge in a pre-filled pen + 8 needles Reg. No. DKI0980501043A1

GONAL-f 900 IU/1.44 mL: Box, 1 cartridge in a pre-filled pen + 20 needles Reg. No. DKI0980501043A1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Date of first authorisation: 31 Jul 2012 (Gonal-f 300 IU, 900 IU), 6 Dec 2021 (Gonal-f 150 IU)
Date of last renewal : 27 Dec 2023

10. CLASSIFICATION OF MEDICINE
Medicinal product subject to medical prescription. Obat Keras.

HARUS DENGAN RESEP DOKTER
On Medical Prescription Only

11. DATE OF REVISION OF THE TEXT
SmPC based on CCDS version 4
Date of BPOM approval for the update: xxxxxx

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

INFORMASI UNTUK PASIEN

GONAL-f
Follitropin alfa

Larutan untuk injeksi dalam *pre-filled* pen

Baca seluruh petunjuk ini dengan hati-hati sebelum mulai menggunakan obat, karena petunjuk ini berisi informasi yang penting untuk Anda.
- Simpan lembar petunjuk ini, Anda mungkin akan memerlukannya kembali.
- Jika Anda mempunyai pertanyaan, harap menghubungi dokter atau apoteker.
- Obat ini diresepkan hanya untuk Anda. Jangan diberikan kepada orang lain karena dapat membahayakan orang tersebut meskipun terdapat gejala yang sama pada orang tersebut.
- Jika Anda mengalami efek samping hubungi dokter atau apoteker. Termasuk efek samping yang tidak terdapat dalam informasi produk. Lihat bagian 4 Efek samping yang mungkin terjadi.

Petunjuk ini terdiri dari informasi sebagai berikut:

1 Apa itu GONAL-f dan apa kegunaannya

Apa itu GONAL-f
GONAL-f mengandung obat yang disebut "follitropin alfa". Follitropin alfa adalah jenis "Follicle Stimulating Hormone" (FSH) atau hormon perangsang folikel yang termasuk dalam keluarga hormon yang disebut "gonadotropin". Gonadotropin terlibat dalam reproduksi dan kesuburan.

Apa Kegunaan GONAL-f
Pada wanita dewasa, GONAL-f digunakan:
- untuk membantu melepaskan sel telur dari ovarium (ovulasi) pada wanita yang tidak dapat berovulasi dan tidak merespon pengobatan dengan obat yang disebut "clomiphene citrate".
- bersama dengan obat lain yang disebut "lutropin alfa" ("Luteinising Hormone" atau LH) atau hormon pelutein untuk membantu melepaskan sel telur dari ovarium (ovulasi) pada wanita yang tidak mengalami ovulasi karena tubuh mereka memproduksi sangat sedikit gonadotropin (FSH dan LH).
- untuk membantu perkembangan beberapa folikel (masing-masing mengandung sel telur) pada wanita yang menjalani prosedur *Assisted Reproductive Technologies* (prosedur yang dapat membantu Anda hamil) seperti "fertilisasi in vitro", "transfer gamet intra-fallopi" atau "transfer zigot intra-fallopi".

Pada pria dewasa, GONAL-f digunakan:
- bersama dengan obat lain yang disebut "human Chorionic Gonadotropin" (hCG) untuk membantu memproduksi sperma pada pria yang tidak subur karena rendahnya kadar hormon tertentu.

2 Apa yang perlu Anda ketahui sebelum Anda menggunakan GONAL-f

Kesuburan Anda dan pasangan Anda harus dievaluasi sebelum pengobatan dimulai oleh dokter yang berpengalaman dalam mengobati gangguan kesuburan.

Jangan gunakan GONAL-f jika Anda:
- alergi terhadap hormon perangsang folikel atau bahan-bahan lain yang terdapat dalam obat ini (lihat bagian *6 Isi dari kemasan dan informasi lain*).

- memiliki tumor pada kelenjar hipotalamus atau hipofisis (keduanya merupakan bagian dari otak).
- **wanita:**
  - memiliki ovarium yang besar atau kista ovarium yang tidak diketahui secara pasti sumbernya.
  - mengalami pendarahan pada organ vagina yang tidak diketahui secara pasti penyebabnya.
  - memiliki kanker ovarium, rahim, atau payudara.
  - memiliki kondisi yang secara lazim membuat kehamilan normal tidak mungkin, seperti menopause atau menopause dini (kegagalan ovarium) atau malformasi organ seksual.
- **pria:**
  - dengan testis yang rusak dan tidak dapat disembuhkan.

Jangan gunakan GONAL-f jika kondisi di atas sesuai dengan kondisi Anda. Jika Anda tidak yakin, diskusikan kepada dokter sebelum menggunakan obat ini.

Peringatan dan Pencegahan

Porfiria

Beri tahu dokter sebelum Anda memulai pengobatan jika Anda atau anggota keluarga Anda menderita porfiria (ketidakmampuan untuk memecah porfirin yang mungkin diturunkan dari orang tua kepada anak-anak).

Beri tahu dokter segera jika:
- kulit Anda menjadi rapuh dan mudah melepuh, terutama kulit yang sering terkena sinar matahari, dan/atau
- perut, lengan atau kaki Anda terasa sakit.

Jika kejadian di atas terjadi, dokter mungkin merekomendasikan Anda untuk menghentikan pengobatan.

Ovarian Hyperstimulation Syndrome (OHSS)/Sindrom Hiperstimulasi Ovarium

Jika Anda seorang wanita, obat ini dapat meningkatkan risiko Anda mengalami OHSS. Kondisi ini adalah ketika folikel Anda berkembang terlalu banyak dan menjadi kista besar.

Jika Anda mengalami nyeri perut bagian bawah, penambahan berat badan dengan cepat, mual atau muntah, atau mengalami kesulitan bernapas, segera konsultasikan dengan dokter yang mungkin meminta Anda untuk berhenti menggunakan obat ini (lihat bagian *4 Efek samping yang mungkin terjadi*).

Jika Anda tidak mengalami ovulasi, dan jika dosis dan jadwal pemberian yang disarankan dipatuhi, maka kemungkinan terjadinya OHSS akan lebih kecil. Pengobatan GONAL-f jarang menyebabkan OHSS parah kecuali jika obat yang digunakan untuk akhir pematangan folikel (mengandung human Chorionic Gonadotropin, hCG) diberikan. Jika Anda mengalami OHSS, dokter mungkin tidak memberikan Anda hCG dalam siklus pengobatan ini dan Anda mungkin diminta untuk tidak berhubungan seks atau menggunakan metode kontrasepsi barrirer (penghalang) selama setidaknya empat hari.

Kehamilan Ganda

Ketika menggunakan GONAL-f, Anda memiliki risiko lebih tinggi untuk hamil dengan lebih dari satu anak pada waktu yang bersamaan (‘kehamilan ganda’, umumnya kembar) jika dibandingkan dengan proses kehamilan secara alami. Kehamilan ganda dapat menyebabkan komplikasi medis untuk Anda dan bayi Anda. Risiko kehamilan ganda dapat berkurang jika Anda menggunakan dosis GONAL-f dengan tepat pada waktu yang tepat. Ketika menjalani teknologi reproduksi berbantuan, risiko kehamilan ganda tergantung pada usia Anda, kualitas dan jumlah sel telur atau embrio yang dibuahi di dalam diri Anda.

Keguguran

Saat menjalani *Assisted Reproductive Technologies* atau menstimulasi ovarium untuk menghasilkan telur, Anda lebih mungkin mengalami keguguran daripada rata-rata wanita.

Gangguan Pembekuan Darah (Tromboembolik)

Jika Anda atau anggota keluarga Anda pernah memiliki riwayat penggumpalan darah di kaki atau paru-paru, atau serangan jantung atau stroke, Anda mungkin berisiko lebih tinggi terhadap penggumpalan darah serius atau gumpalan yang telah ada memburuk dengan penggunaan GONAL-f.

Pria dengan Terlalu Banyak FSH dalam Darah
Jika Anda seorang pria yang memiliki terlalu banyak FSH dalam darah Anda, maka bisa menjadi tanda testis yang rusak. GONAL-f biasanya tidak bekerja jika Anda memiliki masalah ini.

Jika dokter memutuskan untuk mencoba pengobatan GONAL-f, untuk memantau pengobatan, dokter mungkin meminta Anda untuk memberikan sperma Anda untuk dianalisis selama 4 hingga 6 bulan setelah memulai pengobatan.

Anak-Anak
GONAL-f tidak ditujukan untuk digunakan oleh anak-anak.

Obat Lain dan GONAL-f
Beri tahu dokter jika Anda sedang, baru saja, atau mungkin akan menggunakan obat-obatan lain.
- Jika Anda menggunakan GONAL-f dengan obat lainnya yang membantu ovulasi (seperti hCG atau clomiphene citrate), hal ini dapat meningkatkan respon folikel Anda.
- Jika Anda menggunakan GONAL-f pada waktu yang sama seperti agonis atau antagonis "hormon pelepas gonadotropin" (GnRH) (obat-obatan ini mengurangi kadar hormon seks Anda dan menghentikan Anda berovulasi) Anda mungkin memerlukan dosis GONAL-f yang lebih tinggi untuk memroduksi folikel.

Kehamilan dan Menyusui
Jangan gunakan GONAL-f jika Anda sedang hamil atau menyusui.

Mengendarai Kendaraan dan Mengoperasikan Mesin
GONAL-f diperkirakan tidak akan mempengaruhi kemampuan Anda dalam mengendarai kendaraan dan mengoperasikan mesin.

GONAL-f Mengandung Natrium
Obat ini mengandung kurang dari 1 mmol natrium (23 mg) per dosis, sehingga pada dasarnya “bebas natrium”.

3 Bagaimana cara menggunakan GONAL-f

Selalu gunakan obat ini sesuai dengan yang disarankan oleh dokter. Tanyakan kembali pada dokter atau apoteker jika Anda tidak yakin.

Penggunaan Obat Ini
- GONAL-f ditujukan untuk diberikan dengan suntikan tepat di bawah kulit (subkutan). Pen dapat digunakan untuk beberapa kali suntikan.
- Suntikan GONAL-f pertama harus diberikan di bawah pengawasan dokter.
- Dokter atau perawat Anda akan menunjukkan cara menyuntikkan GONAL-f sebelum Anda menyuntik sendiri.
- Jika Anda memberikan GONAL-f pada diri Anda sendiri, harap baca dan ikuti “Petunjuk penggunaan” di akhir brosur ini.

Berapa Banyak yang Digunakan
Dokter akan memutuskan berapa banyak obat yang akan Anda gunakan dan seberapa sering yang Anda menggunakan. Dosis yang dijelaskan di bawah ini dinyatakan dalam International Unit (IU).

Wanita
Jika Anda tidak mengalami ovulasi dan mengalami menstruasi yang tidak teratur atau tidak mengalami menstruasi
- GONAL-f biasanya diberikan setiap hari.

- Jika Anda mengalami menstruasi tidak teratur, mulailah menggunakan GONAL-f dalam 7 hari pertama siklus menstruasi Anda. Jika Anda tidak mengalami menstruasi, Anda dapat mulai menggunakan obat pada hari yang sesuai menurut Anda.
- Dosis umum awal GONAL-f adalah 75 hingga 150 IU setiap hari.
- Dosis GONAL-f Anda dapat ditingkatkan setiap 7 hari atau setiap 14 hari sebesar 37,5 hingga 75 IU, hingga Anda mendapatkan respon yang diinginkan.
- Dosis harian maksimum GONAL-f umumnya tidak lebih tinggi dari 225 IU.
- Ketika Anda mendapatkan respon yang diinginkan, Anda akan diberikan suntikan 250 mikrogram "hCG rekombinan" satu kali (r-hCG, hCG yang dibuat di laboratorium dengan teknik DNA khusus), atau 5.000 hingga 10.000 IU hCG, 24 hingga 48 jam setelah suntikan GONAL-f terakhir Anda. Waktu terbaik untuk berhubungan seks adalah pada hari suntikan hCG dan satu hari setelah suntikan hCG.

Jika dokter tidak dapat melihat respons yang diinginkan setelah 4 minggu, siklus pengobatan dengan GONAL-f harus dihentikan. Untuk siklus pengobatan berikutnya, dokter akan memberi Anda dosis awal GONAL-f yang lebih tinggi daripada sebelumnya.

Jika tubuh Anda merespon terlalu kuat, pengobatan Anda akan dihentikan dan Anda tidak akan diberikan hCG (lihat bagian 2, OHSS). Untuk siklus berikutnya, dokter akan memberi Anda dosis GONAL-f yang lebih rendah daripada sebelumnya.

Jika Anda tidak mengalami ovulasi, tidak mengalami menstruasi dan telah didiagnosis memiliki kadar hormon FSH dan LH yang sangat rendah
- Dosis umum awal GONAL-f adalah 75 hingga 150 IU bersama dengan 75 IU lutropin alfa.
- Anda akan menggunakan dua obat ini setiap hari hingga lima minggu.
- Dosis GONAL-f Anda dapat ditingkatkan setiap 7 atau setiap 14 hari sebesar 37,5 hingga 75 IU, hingga Anda mendapatkan respon yang diinginkan.
- Ketika Anda mendapatkan respon yang diinginkan, Anda akan diberikan suntikan 250 mikrogram "hCG rekombinan" satu kali (r-hCG, hCG yang dibuat di laboratorium dengan teknik DNA khusus), atau 5.000 hingga 10.000 IU hCG, 24 hingga 48 jam setelah suntikan terakhir GONAL-f dan lutropin alfa Anda. Waktu terbaik untuk berhubungan seks adalah pada hari suntikan hCG dan satu hari setelah suntikan hCG.
- Alternatif lain, inseminasi intrauterin dapat dilakukan dengan menempatkan sperma ke dalam rongga rahim.

Jika dokter tidak melihat respons yang diinginkan setelah 5 minggu, siklus pengobatan dengan GONAL-f harus dihentikan. Untuk siklus berikutnya, dokter akan memberi Anda dosis awal GONAL-f yang lebih tinggi daripada sebelumnya.

Jika tubuh Anda merespons terlalu kuat, pengobatan Anda dengan GONAL-f akan dihentikan dan Anda tidak akan diberikan hCG (lihat bagian 2, OHSS). Untuk siklus berikutnya, dokter akan memberi Anda dosis GONAL-f yang lebih rendah daripada sebelumnya.

Jika Anda perlu mengumpulkan beberapa sel telur terlebih dahulu untuk *Assisted Reproductive Technology*
- Dosis umum awal GONAL-f adalah 150 hingga 225 IU setiap hari, mulai dari hari kedua atau ketiga dari siklus pengobatan Anda.
- Dosis GONAL-f dapat ditingkatkan, tergantung pada respon Anda. Dosis harian maksimum adalah 450 IU.
- Pengobatan dilanjutkan hingga sel telur Anda berkembang ke titik yang diinginkan. Hal ini biasanya memakan waktu sekitar 10 hari, namun dapat pula memakan waktu antara 5 dan 20 hari. Dokter akan menggunakan tes darah dan/atau mesin ultrasonik untuk memeriksa waktu perkembangan sel telur.
- Ketika sel telur Anda siap, Anda akan diberikan suntikan 250 mikrogram "hCG rekombinan" satu kali (r-hCG, hCG yang dibuat di laboratorium dengan teknik DNA rekombinan khusus), atau 5.000 IU hingga 10.000 IU hCG, 24 hingga 48 jam setelah suntikan GONAL-f terakhir. Hal ini membuat sel telur Anda siap untuk dikumpulkan.

Dalam kasus lain, dokter mungkin pertama-tama menghentikan ovulasi Anda menggunakan agonis atau antagonis hormon pelepas gonadotropin (GnRH). Kemudian GONAL-f dimulai sekitar dua minggu setelah dimulainya pengobatan agonis. GONAL-f dan agonis GnRH diberikan sampai folikel Anda berkembang sesuai yang diinginkan. Misalnya, setelah dua minggu pengobatan agonis GnRH, GONAL-f 150 hingga 225 IU diberikan selama 7 hari. Dosis kemudian disesuaikan sesuai dengan respon ovarium Anda.

Pria
- Dosis umum GONAL-f adalah 150 IU bersama dengan hCG.
- Anda akan menggunakan dua obat ini tiga kali seminggu selama setidaknya 4 bulan.
- Jika Anda belum merespons pengobatan setelah 4 bulan, dokter mungkin menyarankan agar Anda terus menggunakan dua obat ini selama minimal 18 bulan.

Jika Anda Menggunakan GONAL-f Lebih dari yang Seharusnya
Efek dari menggunakan terlalu banyak GONAL-f tidak diketahui, Namun demikian seseorang dapat menduga Sindrom Hiperstimulasi Ovarium (OHSS) terjadi, yang dijelaskan pada bagian 4. Namun, OHSS hanya akan terjadi jika hCG juga diberikan (lihat bagian 2, OHSS).

Jika Anda Lupa Menggunakan GONAL-f
Jika Anda lupa menggunakan GONAL-f, jangan gunakan dosis dobel untuk menebus dosis yang terlupakan. Bicarakan dengan dokter segera setelah Anda menyadari bahwa Anda lupa menggunakan dosis.

Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan obat ini, tanyakan kepada dokter atau apoteker.

4 Efek samping yang mungkin terjadi

Seperti obat lainnya, obat ini dapat menyebabkan efek samping, walaupun tidak semua pasien akan mengalaminya.

Efek Samping yang Serius pada Wanita
- Nyeri perut bagian bawah bersamaan dengan mual atau muntah mungkin merupakan gejala Sindrom Hiperstimulasi ovarium (OHSS). Hal ini mungkin menunjukkan bahwa ovarium bereaksi berlebihan terhadap pengobatan dan kista ovarium berkembang besar (lihat juga di bagian 2. pada "Sindrom Hiperstimulasi Ovarium"). Efek samping ini umum terjadi (dapat terjadi hingga 1 dari 10 pasien).
- OHSS dapat menjadi parah dengan ovarium yang membesar dengan jelas, penurunan produksi urin, penambahan berat badan, kesulitan bernafas dan/atau kemungkinan akumulasi cairan di perut atau dada Anda. Efek samping ini jarang terjadi (dapat terjadi hingga 1 dari 100 pasien).
- Komplikasi OHSS seperti ovarium yang memutar atau pembekuan darah mungkin jarang terjadi (dapat terjadi hingga 1 dari 1.000 pasien).
- Komplikasi pembekuan darah yang serius (kejadian tromboemboli) kadang-kadang terlepas dari OHSS sangat jarang ditemukan (dapat terjadi hingga 1 dari 10.000 pasien). Hal ini dapat menyebabkan nyeri dada, sesak napas, stroke atau serangan jantung (lihat juga di bagian 2, dalam "Masalah pembekuan darah").

Efek Samping yang Serius pada Pria dan Wanita
- Reaksi alergi seperti ruam, kulit merah, hives, pembengkakan wajah Anda disertai dengan kesulitan bernapas yang kadang-kadang bisa menjadi efek serius. Efek samping ini sangat jarang (dapat terjadi hingga 1 dari 10.000 pasien).

Jika Anda mengalami salah satu efek samping di atas, Anda harus segera menghubungi dokter yang mungkin meminta Anda untuk berhenti menggunakan GONAL-f.

Efek Samping Lainnya pada Wanita
Sangat umum (dapat terjadi hingga 1 dari 10 pasien)
- Kantung cairan di dalam ovarium (kista ovarium)
- Sakit kepala

- Reaksi lokal di tempat suntikan, seperti nyeri, kulit merah, memar, bengkak dan/atau iritasi

Umum (dapat terjadi hingga 1 dari 10 pasien)
- Sakit perut
- Merasa sakit, muntah, diare, kram perut dan kembung

Sangat jarang (dapat terjadi hingga 1 dari 10.000 pasien)
- Reaksi alergi seperti ruam, kulit merah, hives, pembengkakan wajah Anda disertai dengan kesulitan bernapas dapat terjadi. Reaksi-reaksi ini kadang-kadang bisa menjadi serius.
- Asma Anda mungkin memburuk

Efek samping lainnya pada pria
Sangat umum (dapat terjadi hingga 1 dari 10 pasien)
- Reaksi lokal di tempat suntikan, seperti nyeri, kemerahan, memar, bengkak, dan/atau iritasi

Umum (dapat terjadi hingga 1 dari 10 pasien)
- Pembengkakan pembuluh darah di atas dan di belakang testis (varikokel).
- Perkembangan payudara, jerawat atau kenaikan berat badan.

Sangat jarang (dapat terjadi hingga 1 dari 10.000 pasien)
- Reaksi alergi seperti ruam, kulit merah, hives, pembengkakan wajah Anda dengan kesulitan bernafas dapat terjadi. Reaksi-reaksi ini kadang-kadang bisa menjadi serius.
- Asma Anda mungkin memburuk.

Pelaporan efek samping
Jika Anda mengalami efek samping, beritahukan dokter atau apoteker. Hal ini termasuk untuk efek samping yang tidak tercantum dalam petunjuk ini. Dengan melaporkan efek samping, Anda dapat membantu untuk memberikan informasi lebih lengkap terkait dengan keamanan obat ini.

5 Bagaimana menyimpan Gonal-f

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Jangan menggunakan obat ini setelah tanggal kedaluwarsa yang tertera pada label dan dus setelah EXP. Tanggal kedaluwarsa adalah hari terakhir pada bulan yang tertera.

Simpan dalam lemari pendingin (2°C – 8°C). Jangan dibekukan.

Dalam umur simpannya, produk ini dapat disimpan di luar lemari es hingga suhu 25°C untuk satu waktu hingga 3 bulan, serta harus dibuang jika tidak digunakan dalam 3 bulan.

Tetap simpan pen dalam keadaan tertutup untuk melindungi dari cahaya.

Jangan gunakan GONAL-f jika terlihat tanda-tanda kerusakan, jika cairan obat mengandung partikel atau tidak jernih.

Tulis pada pen GONAL-f waktu pemakaian pertama kali. Untuk tujuan ini, telah disediakan stiker pada bagian “Petunjuk penggunaan”.
- Sekali dibuka, pen harus disimpan antara 2°C dan 25°C maksimum 28 hari.
- Jangan gunakan obat yang tertinggal di dalam pen setelah 28 hari.

Setelah pengobatan berakhir, semua larutan yang tidak digunakan harus dibuang.

Jangan buang obat melalui saluran air atau sampah rumah tangga. Tanyakan kepada apoteker bagaimana cara membuang obat yang tidak digunakan. Tindakan ini akan membantu dalam melindungi lingkungan.

6 Isi dari kemasan dan informasi lain

Apa Kandungan GONAL-f

- Zat aktifnya adalah follitropin alfa.
- Terkandung 600 IU (44 mikrogram) follitropin alfa dalam tiap mililiter larutan.
  GONAL-f 150 IU/0.24 mL: Tiap pen dengan *cartridge* multidosis menginjeksi 150 IU (11 mikrogram) dalam 0.24 mL.
  GONAL-f 300 IU/0.48 mL: Tiap pen dengan *cartridge* multidosis menginjeksi 300 IU (22 mikrogram) dalam 0.48 mL.
  GONAL-f 900 IU/1.44 mL: Tiap pen dengan *cartridge* multidosis menginjeksi 900 IU (66 mikrogram) dalam 1.44 mL.
- Bahan lainnya adalah poloxamer 188, sukrosa, methionine, sodium dihydrogen phosphate monohydrate, disodium phosphate dihydrate, m-cresol, concentrated phosphoric acid, sodium hydroxide, dan air untuk injeksi.

Bagaimana Bentuk GONAL-f dan Isi dari Kemasan
- GONAL-f berupa larutan untuk injeksi yang jernih dan tidak berwarna dalam pen.
- Isi dari kemasan:
  GONAL-f 150 IU/0.24 mL: Disediakan dalam kemasan dengan 1 pen dan 4 jarum suntik sekali pakai.
  GONAL-f 300 IU/0.48 mL: Disediakan dalam kemasan dengan 1 pen dan 8 jarum suntik sekali pakai.
  GONAL-f 900 IU/1.44 mL: Disediakan dalam kemasan dengan 1 pen dan 20 jarum suntik sekali pakai.

Produsen
Diproduksi oleh Merck Serono S.p.A., Bari, Italy
Diimpor oleh PT Merck Tbk, Jakarta, Indonesia

Pemilik Izin Edar
Didaftarkan oleh PT Merck Tbk, Jakarta, Indonesia

Kemasan dan Nomor Izin Edar

GONAL-f® 150 IU/~~0.25~~ 0.24 mL, Dus, 1 *pre-filled pen* + 4 jarum suntik	Reg. No. DKI0980501043A1
GONAL-f® 300 IU/~~0.5~~ 0.48 mL, Dus, 1 *pre-filled pen* + 8 jarum suntik	Reg. No. DKI0980501043A1
GONAL-f® 900 IU/~~1.5~~ 1.44 mL, Dus, 1 *pre-filled pen* + 20 jarum suntik	Reg. No. DKI0980501043A1

HARUS DENGAN RESEP DOKTER

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

Tanggal Perubahan Informasi
Informasi Untuk Pasien ini selaras dengan *SmPC based on CCDS version xxxxxx*
Persetujuan BPOM terhadap pembaruan terakhir xxxxxx