

PART III: CONSUMER INFORMATION

GONAL-f® (follitropin alfa for injection)

This leaflet is part III of a three-part "Product Monograph" published when GONAL-f was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about GONAL-f. Contact your doctor or pharmacist if you have any questions about the drug.

This leaflet contains answers to many questions about infertility and the treatments you are receiving with GONAL-f. Please read this information carefully and discuss any questions or concerns you may have with your doctor.

ABOUT THIS MEDICATION

What is GONAL-f?

GONAL-f is follicle-stimulating hormone (FSH) with no urinary proteins, which stimulates oocyte (egg) development in women. GONAL-f is a highly purified recombinant human form of FSH, manufactured using the latest technology with proven effectiveness and safety in clinical studies.

GONAL-f belongs to a group of medicines called "gonadotropins".

What is GONAL-f used for?

GONAL-f is used to stimulate the maturation of follicles in ovulatory patients undergoing Assisted Reproductive Technologies (ART) such as *in vitro* fertilization (IVF). To complete the maturation of follicles, another hormone, hCG (human chorionic gonadotropin), is given.

GONAL-f is also used to stimulate the maturation of follicles in some patients whose menstrual cycle is either irregular or absent. To complete the maturation of follicles another hormone, hCG, is given.

When should GONAL-f not be used?

GONAL-f should **not** be used if you:

- Have high levels of FSH indicating primary ovarian failure
- Have uncontrolled thyroid or adrenal dysfunction
- Are allergic (hypersensitive) or have a history of hypersensitivity to FSH or to any of the other ingredients of GONAL-f
- Are pregnant or breastfeeding
- Have ovarian enlargement or a cyst not due to polycystic ovarian disease (PCO)
- Have a vaginal bleeding of unknown cause
- Have tumours of the ovary, uterus, breast or brain (hypothalamus or pituitary gland)

The medicinal ingredient in GONAL-f:

Follitropin alfa.

The non-medicinal ingredients in GONAL-f:

The non-medicinal ingredients in GONAL-f 75 IU (5.5 µg) single dose vials are: sucrose, disodium phosphate dihydrate, methionine, Polysorbate 20 and sodium dihydrogen phosphate monohydrate. GONAL-f may also contain O-phosphoric acid and/or sodium hydroxide used for pH adjustment.

The diluent provided for reconstitution is Sterile Water for Injection, Ph.Eur./USP.

The non-medicinal ingredients in GONAL-f 450 IU (33 µg) and 1050 IU (77 µg) Multi-Dose vials are: sucrose, disodium phosphate dihydrate, sodium dihydrogen phosphate monohydrate. GONAL-f may also contain O-phosphoric acid and/or sodium hydroxide used for pH adjustment.

The diluent provided for reconstitution is Bacteriostatic Sterile Water for Injection (0.9% Benzyl Alcohol), USP.

What dosage forms of GONAL-f are available?

GONAL-f is available as a lyophilized powder for reconstitution in vials.

GONAL-f is available in 75 IU (5.5 µg) single dose vials and in 450 IU (33 µg) and 1050 IU (77 µg) Multi-Dose vials. Depending on the dosage regimen, the 450 IU (33 µg) vial can also be administered as a single dose injection.

Each box for the single doses contains a vial of medication (white powder), a pre-filled syringe of sterile water for injection, Ph.Eur./USP (liquid) and a needle for mixing and a needle for injection. Each box for the Multi-Dose vial contains a vial of medication (white powder), a pre-filled syringe containing bacteriostatic sterile water for injection, USP, as well as injection syringes.

Is there a difference between GONAL-f 75 IU (5.5 µg) Single Dose vials and the GONAL-f 450 IU (33 µg)/1050 IU (77 µg) Multi-Dose Vials?

Both products contain the same, highly pure rFSH. However, the 1050 IU (77 µg) multi-dose vial contains the equivalent of fourteen 75 IU (5.5 µg) vials and the 450 IU (33 µg) multi-dose vial contains the equivalent of six 75 IU (5.5 µg) vials. The 450 IU (33 µg) and 1050 IU (77 µg) multi-dose presentations are stable for 28 days after reconstitution when stored at room temperature (at or below 25°C).

The GONAL-f Multi-Dose vials are over-filled with 43.7 or 87.4 µg of drug in order to deliver approximately 450 IU (33 µg) or 1050 IU (77 µg) in several smaller daily doses, respectively. It is common for a small amount of drug to be left over in each vial that cannot be retrieved with a syringe. This is normal. Any drug remaining in the vial that cannot be withdrawn should be discarded.

How is GONAL-f administered?

GONAL-f cannot be taken orally because it would be digested in the stomach and for this reason, it must be taken by injection. Due to its high level of purity, GONAL-f is approved for subcutaneous

injection (just under the skin), which is easier and less painful than intramuscular injections (in the muscle). In fact, with professional guidance, you can learn to inject yourself, in the comfort and privacy of your own home.

How is GONAL-f different from other treatments?

Over the years, the gonadotropin drugs used in the treatment of infertility have undergone significant changes and improvements. Many other products that are not derived from recombinant technology contain FSH and varying amounts of LH and urinary proteins.

GONAL-f is produced through rDNA technology and consists only of highly purified rFSH.

How long will one treatment cycle last?

This depends on the average follicular response to therapy. Every treatment cycle is individualized and your doctor will need to carefully evaluate how you respond.

WARNINGS AND PRECAUTIONS

General

To help avoid side effects and ensure proper use, talk to your doctor or pharmacist before you take GONAL-f.

Your fertility should be evaluated before the treatment is started by a doctor experienced in treating fertility disorders.

Porphyria

If you have porphyria or a family history of porphyria, GONAL-f may increase the risk of an acute attack. Tell your doctor immediately if:

- Your skin becomes fragile and easily blistered, especially skin that has been frequently in the sun, and/or
- You have stomach, arm or leg pain.

In case of the above events your doctor may recommend that you stop treatment.

Overstimulation of the Ovary During FSH Therapy

Ovarian Enlargement

Use of FSH therapy to stimulate follicular development may result in the growth of more than one follicle. This may result in mild to moderate uncomplicated ovarian enlargement which may be accompanied by abdominal distention and/or abdominal pain. It is more commonly seen in women with polycystic ovarian syndrome.

Ovarian Hyperstimulation Syndrome (OHSS)

Treatment increases your risk of developing ovarian hyperstimulation syndrome (OHSS). This is when multiple follicles develop and may become large cysts. In rare cases, severe OHSS may be life-threatening. OHSS may cause fluid build-up in your abdominal and chest areas and can cause blood clots to form. Call your doctor right away if you notice severe

abdominal swelling, pain in the stomach area (abdomen), feeling sick (nausea), vomiting, sudden weight gain due to fluid build-up, diarrhea, decreased urine output or trouble breathing. However, if you follow your doctor's instructions for the recommended dose and schedule of administration, the occurrence of OHSS is uncommon. GONAL-f treatment seldom causes significant OHSS unless the medicine used to induce final follicular maturation and ovulation (containing human chorionic gonadotropin or hCG) is administered. In cases where OHSS is developing it is recommended to not give hCG, and women should prevent pregnancy at this time by not having sexual intercourse.

Breathing and Blood Clotting

Serious breathing problems (e.g., lung collapse, extreme shortness of breath and worsening of asthma) have been reported with use of gonadotropin therapy.

Treatment with gonadotropin therapy may increase the risk of having a blood clot (thrombosis) which may or may not be associated with Ovarian Hyperstimulation Syndrome. Blood clots can lead to serious medical conditions, such as blockage in the lungs (pulmonary embolus), blood vessel problems (thrombophlebitis), heart attack, stroke, blockage in the arteries in your arms and legs which may result in a loss of your arm or leg. In rare cases, lung complications and/or blood clots have resulted in death.

Reproductive Issues

Since women with infertility undergoing assisted reproduction, particularly IVF, may have tubal abnormalities, the incidence of ectopic pregnancies (pregnancy in the fallopian tubes) might be increased. Early ultrasound to confirm that a pregnancy is in the uterus is important.

Miscarriages may be higher than in the normal population, but comparable with the rates found in women with fertility problems.

Reports of multiple births have been associated with fertility treatments. You should discuss the potential risk of multiple births with your doctor before beginning treatment.

The incidence of multiple births with GONAL-f is no different from any other gonadotropin and is dependent upon the protocol used by the clinic. Your doctor will monitor you closely to help minimize the possibility of a multiple pregnancy. The majority of births (about 80%) are single babies. Of those women who do have multiple births, the majority of these are twins. Only very few women conceive 3 or more babies. Even so, neither single nor multiple births can be guaranteed.

There have been reports of ovarian and other reproductive system tumours in women who have had infertility treatment. It is not known if treatment with fertility medicines increase the risk of these tumours in infertile women.

INTERACTIONS WITH THIS MEDICATION

GONAL-f is often used with other medicines to stimulate ovulation (e.g. hCG and LH) which may help the maturation of follicles. If a GnRH agonist or antagonist medicine is also given along with your GONAL-f in your treatment program, you may be told by your doctor to change your dose of GONAL-f. No other significant interactions with other medicines have been reported.

PROPER USE OF THIS MEDICATION

Always take GONAL-f exactly as your doctor has instructed you. You should check with your health care provider if you are unsure.

Recommended Dose

Every treatment is individualized. Your treatment has been carefully designed for you by your doctor. Over the course of your treatment, doses may range between 75 to 450 IU depending on your specific medical condition and your response to the medicine.

Overdose

What should I do if I accidentally inject more than my prescribed amount of GONAL-f?

The effects of an overdose of GONAL-f are unknown. You should contact your doctor for advice if you take more than your prescribed dose of GONAL-f.

Missed dose

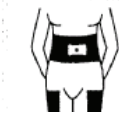
What should I do if I forget to take my GONAL-f?

Do not take a double dose to make up for any doses you have missed. Contact your doctor for advice if you forget to take a dose of GONAL-f.

Where should I inject GONAL-f?

The most easily accessible areas for subcutaneous injection are the abdomen and thighs. The absorption of GONAL-f is the same regardless of the injection site selected. You may find the injection is more comfortable if you vary the site each time you inject GONAL-f.

Below is a diagram with shaded areas demonstrating the recommended subcutaneous injection sites.



HOW TO INJECT GONAL-f

A Step by Step Guide

Understandably, you may be a little apprehensive at first about giving yourself an injection. That is why this information has been produced. Refer to it as necessary and follow each instruction step by step. If you have any questions or concerns that are not addressed here, please consult your clinic.

Every treatment is individualized. Yours has been carefully designed for you by your doctor according to your own specific needs. It is very important that you keep your appointments and follow your doctor's instructions, particularly with regard to the amount and frequency of the medication you are taking. If you have concerns regarding your dosage, consult your doctor. Do not adjust your dosage without being instructed to do so. If you forget or miss an injection, do not panic, but you should call your doctor for advice.

IMPORTANT POINTS TO REMEMBER

Always follow the basic principles of self injection:

- It is recommended that you inject GONAL-f at around the same time each day.
- Use a clean work surface and clean skin as directed.
- Always check expiry date before use. Never use expired GONAL-f.
- Check dosage and instructions for mixing.
- Be sure to use the correct strength and correct amount of diluent.
- Check medication after reconstitution - do not use if medication is cloudy, lumpy or discoloured.
- Alternate injection sites each day.
- Check and record site of injections each day.

If you are unsure about the mixing of the solution, or have difficulty with the injections, call Momentum at 1-800-387-8479 or your clinic immediately.

***For instructions on how to administer GONAL-f (follitropinalfa for Injection) 450 IU (33 µg) or 1050 IU (77 µg) Multi-Dose vials, please read INSTRUCTIONS FOR USING GONAL-f 450 IU (33 µg) or 1050 IU (77 µg) MULTI-DOSE VIAL.**

INSTRUCTIONS FOR USING GONAL-f (follitropin alfa for Injection) 75 IU (5.5 µg) SINGLE DOSE VIALS

Please read through the following instructions before you begin, in order to become familiar with self-administration of GONAL-f. *If you have been prescribed GONAL-f single dose vials, but the diluent is in a vial, please see your clinic for the specific reconstitution steps.*

Please note that µg is pronounced "microgram" and is a unit of measure. 1 gram is equivalent to 1 million micrograms.

1. GETTING READY

- On a clean work surface, lay out everything you will need:
 - GONAL-f mono-dose vial(s) of white powder
 - Diluent in pre-filled syringe
 - One needle for reconstitution (mixing)
 - One ½ inch, 25, 27 or 29 gauge needle for injection
 - Two alcohol wipes
 - Needle disposal container
- If you use your kitchen to prepare the injection, ensure that all medicines and needles are kept well away from food. As for the injection itself, it can be given in any room where you feel comfortable.

2. CLEANSE

- Before you start, wash your hands well with soap and water. It is important that your hands and the items you use be as clean as possible.
- Needles should not touch any surface except inside the vials and alcohol-cleaned skin; keep them capped prior to use.
- Make sure you use a new needle each time you inject to avoid contamination.

3. PREPARE THE PRE-FILLED SYRINGE OF DILUENT

- Carefully twist off the cap at the tip of the barrel of the pre-filled syringe.
- Remove the mixing needle from its package, being careful to keep the protective needle cap in place.
- Carefully twist the mixing needle onto the barrel of the pre-filled syringe until it is tightened.
- Carefully lay the syringe down on a flat, clean, surface.

Reconstitution Volumes

Volumes used for reconstitution should be between 0.5 and 1.0 mL; up to 225 IU (16.5 µg) may be dissolved in 0.5 ml of diluent (Sterile Water for Injection, USP). Following reconstitution, the medication in the vials should be used immediately, and any unused solution should be discarded.

4. MIXING GONAL-f SINGLE DOSE VIAL(S)

- You should have a set number of vials, as prescribed by your doctor, containing GONAL-f (white powder).
- Using your thumb, flip off the plastic cap of the GONAL-f vial.
- Continue to open all vials in this manner, if required.
- Wipe the rubber stopper on the top of the vial with an alcohol wipe.
- Carefully twist the needle cap off the pre-filled syringe labelled "Sterile Water for Injection, USP" prepared in previous step 3.
- Position the needle in a straight, downward position over the marked centre circle of the rubber stopper on the vial of GONAL-f powder.
- Keep the needle in a straight, downward position as you insert it through the centre circle or it may be difficult to depress the plunger.
- Slowly inject the liquid into the vial by pushing the

syringe plunger down (volume to be confirmed by your physician). The sterile water and white powder will mix to form a clear liquid.

- Do not shake the vial. If bubbles appear, wait a few moments for the bubbles to settle.
- **DO NOT USE IF SOLUTION APPEARS CLOUDY, LUMPY or DISCOLOURED.** Report this and the lot number to your doctor.
- When all of the sterile water (diluent) has been injected into the vial, keep the needle in the vial, lift the vial and turn it upside down with the needle pointing toward the ceiling. With the needle tip in the liquid, slowly pull back the plunger until the vial is empty. Be careful not to pull the plunger out of the syringe. Remove the needle from the vial.
- **If you have been prescribed more than one vial of GONAL-f, repeat the points above using the mixed solution in the syringe to dissolve the next vial. Continue in the same manner until you have the prescribed number of powder vials dissolved in the solution.**
- Discard empty vials in the needle disposal container.

5. REMOVE AIR BUBBLES AND CHANGE NEEDLE

- Hold the syringe with the needle pointing upwards and gently flick the syringe if there are any visible air bubbles. The air bubbles will collect at the top of the syringe. If there are no air bubbles, or if there is no air space at the top of the syringe, pull the plunger back to allow an air space.
- Recap the needle and twist to remove; replace with the ½ inch, 25, 27 or 29 gauge injection needle with cap. Lay syringe down on the clean surface.
- Do not worry if you are unable to remove very tiny bubbles; they will do no harm. When you invert the syringe, the air space will be next to the plunger. This space will ensure that all of the medication has been injected. The air will remain in the needle.

6. PREPARE THE INJECTION SITE

- Select the site of injection (e.g. top of thigh, tummy).
- Wipe the chosen area with an alcohol wipe, cleansing an area of approximately 5 cm x 5 cm.
- Lay the used side of the wipe next to your working surface or on the alcohol wipe wrapper.

7. INJECTING THE SOLUTION

- Pick up the syringe and remove the cap from the needle.
- Invert the needle and hold as if throwing a dart.
- With your other hand, gently squeeze the skin together to make a little elevation at the injection site.
- Using a "dart like motion", insert the needle at a 90-degree angle. (You need very little force but quick action.)
- Once the needle is inserted into the tissue all the way, inject the solution by pushing gently on the plunger with your thumb or index finger of the hand holding the syringe. Take as much time as you need to inject all the solution.

- Immediately withdraw the needle and clean the site with the clean side of the alcohol swab using a circular motion. If there is minor oozing you may need to apply a small amount of pressure for a minute.

8. DISPOSE OF ALL USED ITEMS

- Once you have finished your injection, immediately discard the needles and syringe (without recapping the needle) into the disposal container.
- Take the container to a clinic or pharmacy for proper disposal when the needle disposal container is full or when you have completed your entire treatment.

***For instructions on how to administer GONAL-f (follitropin alfa for Injection) 75 IU (5.5 µg) please read "INSTRUCTIONS FOR USING GONAL-f 75 IU (5.5 µg) SINGLE DOSE VIALS"**

INSTRUCTIONS FOR USING GONAL-f (follitropin alfa for Injection) 450 IU (33 µg) or 1050 IU (77 µg) MULTI-DOSE VIALS

GONAL-f 450 IU (33 µg) or 1050 IU (77 µg) Multi-Dose has been prescribed for you by your doctor to treat infertility. To help you prepare and use this medicine, you should read these instructions carefully and ask your doctor to explain anything you do not understand.

1. GETTING READY

Make sure you have all the necessary items listed below before you begin:

- Three alcohol wipes
- Single, prefilled syringe labelled "Bacteriostatic Sterile Water for Injection, USP"
- Vial containing GONAL-f 450 IU (33 µg) or 1050 IU (77 µg) Multi-Dose (white powder)
- One 27-gauge syringe for injection with unit dose markings from 37.5 IU (2.8 µg) FSH to 600 IU (44 µg) FSH for use with the GONAL-f Multi-Dose vials
- Needle disposal container

2. MIXING GONAL-f 450 IU (33 µg) or 1050 IU (77 µg) MULTI-DOSE VIAL

- Wash your hands with soap and water.
- Using your thumb, flip off the plastic cap of the GONAL-f 450 IU (33 µg) or 1050 IU (77 µg) Multi-Dose vial.
- Wipe the top of the vial stopper with an alcohol wipe.
- Carefully twist the needle cap off the syringe labelled "Bacteriostatic Sterile Water for Injection, USP". Do not touch the needle or allow the needle to touch any surface.
- Position the needle of the syringe of bacteriostatic sterile water in a straight, downward position over the marked centre circle of the rubber stopper on the vial of GONAL-f 450 IU (33 µg) or 1050 IU (77 µg) Multi-Dose powder. Keep the needle in a straight, downward

position as you insert it through the centre circle or it may be difficult to depress the plunger.

- Slowly inject the bacteriostatic sterile water into the vial by pushing the syringe plunger down. When all the bacteriostatic sterile water has been injected into the vial, withdraw the syringe and safely dispose of it immediately in your disposal container. Do not use the syringe to inject your dose. The bacteriostatic sterile water and white powder will mix to form a clear liquid.
- Do not shake the vial. If bubbles appear, wait a few moments for the bubbles to settle. The liquid drug should be clear.
- DO NOT USE IF SOLUTION APPEARS CLOUDY, LUMPY or DISCOLOURED. Report this and the lot number to your doctor.
- Once reconstituted, write the date of reconstitution on the vial or box in order to keep track of its 28-day shelf-life.

3. DETERMINING YOUR DOSE ON THE INJECTION SYRINGE

Your doctor will instruct you to take a specific dose of GONAL-f 450 IU (33 µg) or 1050 IU (77 µg) Multi-Dose. Your doctor will show you how to locate the syringe marking that corresponds to your prescribed dose.

IMPORTANT: If your doctor instructs you to increase or decrease your dose for one or more days, find the correct dose marking on the injection syringe and make the change as directed. Contact your clinic office if you have questions.

4. PREPARING YOUR DOSE

- Wipe the rubber stopper of the vial of GONAL-f Multi-Dose with an alcohol wipe.
- Carefully pull the cap from the needle for injection. Do not touch the needle or allow the needle to touch any surface. Firmly hold the vial of GONAL-f 450 IU (33 µg) or 1050 IU (77 µg) Multi-Dose liquid on a flat surface and insert the needle straight and through the marked center circle of the rubber stopper.
- Keeping the needle in the vial, lift the vial and turn it upside down with the needle pointing toward the ceiling. With the needle tip in the liquid, slowly pull back the plunger until the syringe fills to slightly more than the mark for your prescribed dose. Next, keeping the needle in the vial, slowly adjust the plunger to your prescribed dose-this will clear away any air bubbles.
- Check that you have the plunger set at your prescribed dose.

IMPORTANT: During your treatment, if you are required to reconstitute another Multi-Dose vial, please read instructions found in the box below; otherwise, please follow through to the next bullet point.

If you have used less than 450 IU (33 µg) or 1050 IU (77 µg) but the amount remaining is insufficient to complete your next dose, follow these steps to maintain sterility:

1. Verify the amount remaining in the vial currently in use by referencing your dose log; or, if necessary, by withdrawing the remaining liquid into a syringe for injection, making note of the exact volume, and returning it to the vial.
2. Discard empty syringe.
3. Reconstitute the new vial as directed in step "Mixing GONAL-f Multi-Dose vials".
4. Calculate the amount to withdraw from the new vial by subtracting the amount left in the current vial from the desired dose (as prescribed by your physician).
5. Use a new syringe for injection to withdraw the calculated amount from new vial.
6. Insert this partially filled new syringe for injection into the previous vial then draw up your complete dose.

- Remove the syringe needle from the vial. Recap the syringe needle. Do not touch the needle or allow the needle to touch any surface. Carefully lay the syringe down on a flat, clean surface. You should now be ready to prepare the injection site and inject your prescribed dose.

5. PREPARE THE INJECTION SITE

- Select the site of injection (e.g. top of thigh, tummy).
- Wipe the chosen area with an alcohol wipe, cleansing an area of approximately 5 cm x 5 cm. Lay the used side of the wipe next to your working surface or on the alcohol wipe wrapper.

6. INJECTING THE SOLUTION

- Pick up the syringe and remove the cap from the needle.
- Invert the needle and hold as if "throwing a dart".
- With your other hand, gently squeeze the skin together to make a little elevation at the injection site. Using a "dart like motion", insert the needle at a 90-degree angle (You need very little force but quick action).
- Once the needle is inserted into the tissue all the way, inject the solution by pushing gently on the plunger with your thumb or index finger of the hand holding the syringe. Take as much time as you need to inject all the solution.
- Immediately withdraw the needle and clean the site with the clean side of the alcohol swab using a circular motion. If there is minor oozing you may need to apply a small amount of pressure for a minute.

IMPORTANT: The injection syringes provided with GONAL-f 450 IU (33 µg) or 1050 IU (77 µg) Multi-Dose are designed for use only with this product. Do NOT use the injection syringes to administer other drugs or hormones. All used syringes should be discarded.

7. DISPOSE OF USED ITEMS

- Once you have finished your injection, immediately discard the needles and syringe (without recapping the

needle) into the disposal container.

- Take the container to a clinic or pharmacy for proper disposal when the needle disposal container is full or when you have completed your entire treatment.

8. STORING YOUR VIAL OF GONAL-f [450 IU (33 µg) or 1050 IU (77 µg) MULTI-DOSE] BETWEEN USES

- After each use, the vial containing GONAL-f 450 IU (33 µg) and 1050 IU (77 µg) Multi-dose liquid can be stored at room temperature (at or below 25°C).
- Do not freeze. Do not store the drug in the syringe.
- Discard any unused liquid GONAL-f 450 IU (33 µg) or 1050 IU (77 µg) Multi-Dose after 28 days.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Are there any side effects with gonadotropin therapy?

Fertility drugs are safe to take with close monitoring by your doctor. As with all medication, there is a potential for side effects.

The following side effects have been reported with the use of GONAL-f during clinical trials and post-market use:

Common and Very Common: may affect 1 to 10 users in 100

- Ovarian cysts
- Mild to moderate ovarian enlargement
- Breast tenderness
- Mild to moderate OHSS
- Mild to severe injection site reaction (such as pain, redness, bruising, swelling and/or irritation)
- Headache
- Stomach pain or bloating
- Feeling sick (nausea), vomiting, diarrhea

Uncommon, Rare and Very Rare: may affect less than 1 to 10 users in 1,000

- Severe OHSS
- Blood clots (thrombosis)
- Difficulty breathing (acute pulmonary distress)
- Worsening of asthma
- Mild to severe allergic reactions (hypersensitivity) such as rash, red skin, hives, swelling of your face with difficulty breathing may occur. These reactions can sometimes be serious.

The greatest concern your doctor will have is ovarian hyperstimulation syndrome (OHSS). To avoid the development of OHSS, your doctor will carefully monitor your response to GONAL-f. Ovarian enlargement, sometimes accompanied by abdominal bloating and pain, may occur in about 20% of women taking gonadotropins. This is generally reversed with cessation of treatment and severe life-threatening cases are rare.

A causal relationship between treatment with fertility drugs and ovarian cancer has not been established.

The following medical events have been reported subsequent to

pregnancies resulting from gonadotropin therapy in controlled clinical trials: spontaneous abortion, tubal pregnancy, premature labour, postpartum fever and congenital abnormalities.

None of these events were thought to be drug-related. The incidence is not more than that found in the general population.

This is not a complete list of side effects. If you experience any unusual symptoms or side-effects while taking GONAL-f, you should report them to your doctor or pharmacist immediately. It is also wise to discuss the possibility of side effects with your doctor before you begin treatment.

HOW TO STORE IT

GONAL-f vials of lyophilized powder are stable when stored at or below room temperature (25°C) and protected from light.

Do not freeze.

Do not use the product after the expiry date indicated on the label.

Reconstituted Product

Check medication after reconstitution - do not use if medication is cloudy, lumpy or discoloured.

GONAL-f 75 IU (5.5 µg) Single Dose Vials

Following reconstitution, the medication in the vials should be used immediately, and any unused solution should be discarded.

GONAL-f 450 IU (33 µg) or 1050 IU (77 µg) Multi-Dose Vial

After each use, the vial containing GONAL-f 450 IU (33 µg) and 1050 IU (77 µg) Multi-Dose liquid can be stored at room temperature (at or below 25°C).

Do not freeze. Do not store the drug in the syringe.

Discard any unused liquid GONAL-f 450 IU (33 µg) or 1050 IU (77 µg) Multi-Dose after 28 days.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Report Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
 - Canada Vigilance Program
 - Health Canada
 - Postal Locator 0701D
 - Ottawa, Ontario
 - K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Website at: www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained from:

EMD Serono, A Division of EMD Inc., Canada.
2695 North Sheridan Way, Suite 200
Mississauga ON L5K 2N6

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