

## PART III: CONSUMER INFORMATION

### GONAL-f<sup>®</sup> PEN (follitropin alpha for injection)

This information is part III of a three-part “Product Monograph” published when GONAL-f<sup>®</sup> Pen was approved for sale in Canada and is designed specifically for Consumers. This is only a summary and does not contain all information about GONAL-f<sup>®</sup> Pen. Contact your doctor or pharmacist if you have any questions about the drug.

This booklet is designed to help you self-administer GONAL-f<sup>®</sup> solution for injection using the prefilled Pen and to answer many of the questions you may have on infertility and GONAL-f<sup>®</sup> therapy.

#### ABOUT THIS MEDICATION

##### What is GONAL-f<sup>®</sup> ?

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

It is provided in liquid formulation in the prefilled Pen, for easy administration under the skin (subcutaneous injection).

##### What is GONAL-f<sup>®</sup> used for?

GONAL-f<sup>®</sup> (follitropin alpha for injection) 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<sup>®</sup> 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<sup>®</sup> not be used?

GONAL-f<sup>®</sup> should **not** be used if:

- you are hypersensitive to FSH or to any of the other ingredients of GONAL-f<sup>®</sup>
- you have tumours of the hypothalamus and pituitary gland
- you are pregnant or breastfeeding
- you have ovarian enlargement or a cyst not due to polycystic ovarian disease (PCO)
- you have a gynaecological bleeding of unknown cause
- you have ovarian, uterine or breast cancer.

##### How is GONAL-f<sup>®</sup> administered?

Due to its high level of purity, GONAL-f<sup>®</sup> 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 do your own injections in the comfort and privacy of your own home.

##### Why is GONAL-f<sup>®</sup> provided in the prefilled Pen?

The GONAL-f<sup>®</sup> is provided in the prefilled pen to help you easily self-administer accurate and consistent GONAL-f<sup>®</sup>. It is designed so that it is easy to read and set the dosage dial confirmation before injecting the medication. The pen reservoir is clear so that the amount of medication available in the Pen can be seen at all times.

##### The nonmedicinal ingredients of GONAL-f<sup>®</sup> are:

Poloxamer 188, sucrose, L-methionine, sodium dihydrogen phosphate monohydrate, disodium phosphate dihydrate, m-cresol, phosphoric acid, sodium hydroxide and water for injection. This product does not contain latex.

##### What dosage forms of GONAL-f<sup>®</sup> are available?

GONAL-f<sup>®</sup> Pens are available as a solution in a cartridge pre-assembled in a multi-use disposable prefilled pen, ready to use.

GONAL-f<sup>®</sup> Pens are available in the following dosage forms:

- 300 IU/0.5 mL (22 µg/0.5 mL)
- 450 IU/0.75 mL (33 µg/0.75 mL)
- 900 IU/1.5 mL (66 µg/1.5 mL)

#### WARNINGS AND PRECAUTIONS

Treatment increases your risk of developing ovarian hyperstimulation syndrome (OHSS). However, if you follow your doctor’s instructions for the recommended dose and schedule of administration, the occurrence of OHSS is uncommon. GONAL-f<sup>®</sup> treatment seldom causes significant OHSS unless the medicine used to induce final follicular maturation and ovulation (containing human chorionic gonadotropin - 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.

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.

There have been isolated reports of non-serious allergic reactions to GONAL-f<sup>®</sup>. If you had this type of reaction to similar medicines, inform your doctor.

The incidence of multiple births with GONAL-f<sup>®</sup> 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.

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

## INTERACTIONS WITH THIS MEDICATION

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

## PROPER USE OF THIS MEDICATION

Understandably, you may be a little anxious 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.

Always take GONAL-f<sup>®</sup> exactly as your doctor has instructed you. You should check with your health care provider if you are unsure. Before starting to use your pen, please read these instructions the whole way through first. This pen has been prescribed for you – do not let anyone else use it. The numbers on the dose display are measured in International Units or IU. Your doctor would have told you how many IUs to inject each day. Give yourself the injection at the same time each day.

### 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.

The GONAL-f<sup>®</sup> Pens have been designed to allow simple and flexible dosing that covers most treatment protocols or dosing regimens.

### Overdosage:

If you have accidentally injected too much GONAL-f, do not panic. Simply contact your physician or healthcare professional for further instructions.

### Missed dose

*What should I do if I forget to take my GONAL-f<sup>®</sup>?*

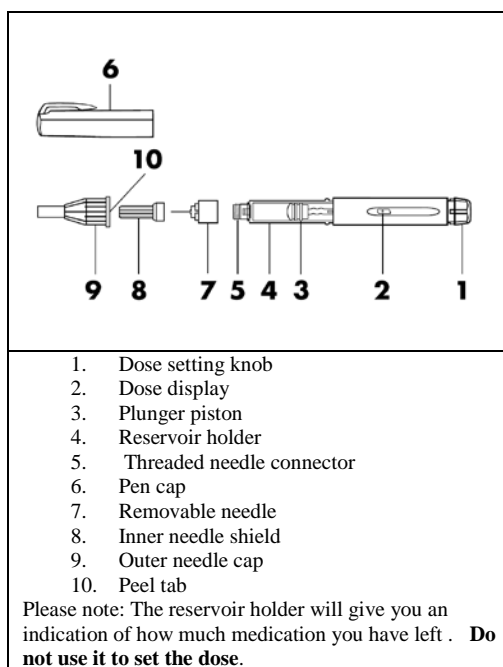
Do not take a double dose to make up for any doses you have missed. Contact your doctor for advice if you forget to take a dose of GONAL-f<sup>®</sup>.

### Where should I inject GONAL-f<sup>®</sup>?

The most easily accessible areas for subcutaneous injection are the abdomen and thighs. The absorption of GONAL-f<sup>®</sup> 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<sup>®</sup>.



GONAL-f<sup>®</sup> prefilled Pen:



### Getting Ready

Wash your hands with soap and water. It is important that your hands and the items you use be as clean as possible.

On a clean work surface, e.g. clean table or kitchen surface, lay out everything you will need: GONAL-f<sup>®</sup> Pen, one injection needle (1/2 inch 29 gauge), 2 alcohol swabs, needle disposal container. [Use the single-use disposable needles provided within the GONAL-f<sup>®</sup> Pen box.]

### Preparing Gonalf<sup>®</sup> Pen for first time use:

- Remove the pen cap and attach a needle as described in Step 1 (How to use the GONAL-f<sup>®</sup> Pen in 3 easy steps).
- Look carefully at the reservoir holder.
- If you don't notice a large air bubble, the pre-filled pen is ready for use. Please go straight to Step 2 "Setting your dose". If you see a large air bubble inside the reservoir you need to remove it. An air bubble is large if it fills fully the tip of the reservoir when holding the pre-filled pen with the needle pointing upwards. Small air bubbles that stick to the inner wall of the reservoir do not need to be removed. They are not harmful.

To remove a large air bubble:

- Gently turn the dose setting knob clockwise until it reads

25 IU preceded by a dot (◐) in the dose display. If you pass this position, simply turn the dose setting knob back to 25 and dot (◐).

- Carefully remove the outer needle cap and the inner needle shield and hold the pen with the needle pointing upwards. [Do not throw away the outer needle cap; you will need it for removing the needle from the pre-filled pen.]
- Tap the reservoir holder gently with your finger so that any air bubbles rise up towards the needle. With the needle still pointing upwards, press slowly the dose setting knob as far as it will go.
- A drop of liquid must appear at the tip of the needle; this shows that your pre-filled pen is ready for injection. The amount of liquid seen at the needle tip is part of the overflow from the pre-filled pen
- Now go to Step 2 “Setting your dose”.(How to use the GONAL-f<sup>®</sup> Pen in 3 easy Steps).

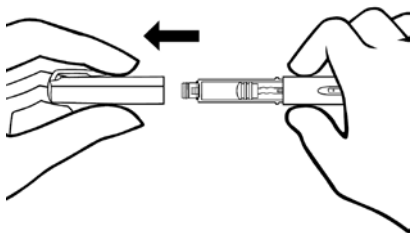
**Note: This step ‘Preparing Gonalf<sup>®</sup> Pen for first time use’ does not need to be repeated again while you are using the same pen.**

For your next injection, attach a needle and set the dose, as described in Step 1 and 2 (How to use the GONAL-f<sup>®</sup> Pen in 3 easy Steps).

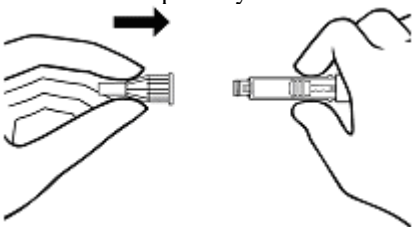
### How to use the GONAL-f<sup>®</sup> Pen in 3 easy steps:

#### Step 1. Uncap pen and put needle on.

- Take the pen cap off. Wipe the end of the threaded tip (containing the rubber center) using an alcohol swab.



- Take a new needle – only use the “single-use” needles supplied for the GONAL-f pre-filled pen.
- Check that the peel-off seal on the outer needle cap is not damaged or loose. (If it is damaged or loose, do not use the needle and get another one. Throw away the unused needle with the outer needle cap still on. Ask your health care provider how to dispose of needles that are no longer required).
- Remove the peel tab from the outer needle cap.
- Hold the outer needle cap firmly.



- Press the threaded tip of the pen into the outer needle cap and twist it clockwise until it is securely fixed.

#### Step 2. Setting your dose

Gently turn the dose setting knob clockwise until you can read your dose through the dose display. Do not push or pull the dose setting knob while you turn it.



If you pass your dose simply turn the dose setting knob back to the correct dose. To adjust the dose, you can turn the dose dial either clockwise or counter-clockwise.

The maximum dose that you can set are:

- 300 IU GONAL-f<sup>®</sup> (Filled by Mass) Pen: 300 IU
- 450 IU GONAL-f<sup>®</sup> (Filled by Mass) Pen: 450 IU
- 900 IU GONAL-f<sup>®</sup> (Filled by Mass) Pen: 450 IU

#### Step 3. Injecting your medication.

Select the site of injection (example: top of thigh or abdomen) making sure to choose a different site each day. Choosing a different injection site each day may minimise skin irritation. Wipe the chosen area with an alcohol wipe, cleansing an area of about 5 cm x 5 cm. Allow the alcohol to dry. Set the alcohol wipe to the side.

Check again the dose shown in the dose display. If it is not the correct dose, you must adjust it by turning the dose setting knob either clockwise or counter-clockwise (see step 2 “Setting your dose”).

If not already done in step “Preparing Gonalf<sup>®</sup> Pen for first time use”, remove the outer needle cap and the inner needle shield from the needle.

[Do not throw away the outer needle cap; you will need it for removing the needle from the pre-filled pen.]

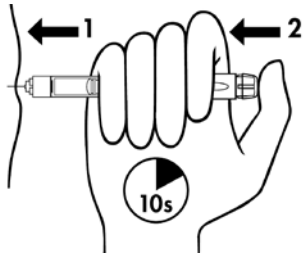
Holding the pen in one hand, use your other hand to gently squeeze the skin together to make a raised area at the injection site.

Use the injection technique as advised by your medical practitioner or nurse. Slowly insert the needle at a 90-degree angle into the skin and press the dose setting knob as far as it will go. (You must keep the needle in the skin with the dose setting knob pressed down for at least 10 seconds.)

The dose number shown in the dose display will turn back to 0. This indicates that the complete dose was delivered.

See step “After the injection - Making sure you have given a complete injection” for details.

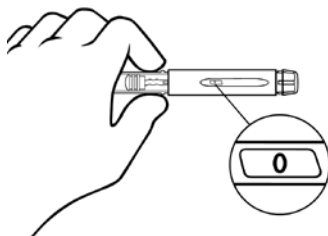
After 10 seconds, keep the dose setting knob pressed down while removing the needle from your skin.



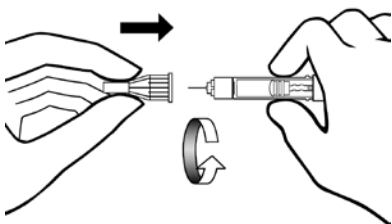
Use the clean side of your alcohol swab to gently clean the injection site. If there is minor oozing you may need to apply a small amount of pressure for a few seconds.

### After the injection

1. Making sure you have given a complete injection
  - Check that the dose display shows 0. This confirms that the dose has been completed correctly.



- **CAUTION: If the dose display shows a number higher than 0, this indicates that the pre-filled pen is empty and that the complete dose has not been given.** If this happens, the number shown in the dose display indicates **the missing amount** of GONAL-f solution that is needed to complete your dose. This is the dose you need to inject using a new pre-filled pen.
  - To complete your dose, follow the steps described above from “Before you start using the pre-filled pen” through to step “Preparing Gonal-f® Pen for first time use” inclusive. After preparing the pen as described in “Before you start using the pre-filled pen” through to step “Preparing Gonal-f® Pen for first time use” above, set the dose to the missing amount displayed on the empty pen that you have just finished and inject this amount.
2. Removing the needle
    - Remove the needle after each injection.
      - Hold the pre-filled pen firmly by the reservoir holder.
      - Carefully replace the outer needle cap onto the needle.



- Grip the outer needle cap and unscrew the needle –

do this by turning it anti-clockwise.

- Be careful not to prick yourself with the needle.
- Dispose of the used needle safely (ask your health care providers how to dispose of needles that are no longer required).
- Put the pen cap back onto the pen.
- Never reuse any needles. Never share needles.
- Please note: your clinic may provide you with a special sharps container designed for GONAL-f. If you have received that special GONAL-f sharps container, simply follow the steps to remove the needle that are outlined on the box.

**CAUTION: Always remove the needle from the pre-filled pen before putting the pen cap back on.** Never store the pen with the needle still attached. The pen cap cannot fit over a pre-filled pen with a needle attached.

3. Storing the pre-filled pen
  - Ensure the needle has been removed
  - Ensure the pen cap is on the pen
  - Protect from light (see also “How to store GONAL-f”).
  - Store the pen in a safe place.

### SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As with all medication, there is a potential for side effects. Some patients undergoing gonadotropin therapy may experience some breast tenderness, fatigue, bloating, weight gain, nausea or diarrhea. These are temporary and will resolve once treatment is stopped. Other adverse reactions may include allergic sensitivity such as a rash and local swelling at the injection site.

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.

This is not a complete list of side effects. If you experience any unusual symptoms or side-effects, you should report them to your doctor immediately.

### HOW TO STORE IT

GONAL-f® Pen may be stored by the patient between 2 and 25°C (in the refrigerator or at room temperature) for a single period of not more than 3 months. After first use, the pen may be stored at 25°C (room temperature) for a maximum of 28 days.

Do not use the GONAL-f® prefilled pen if the solution contains particles or is not clear.

Do not freeze. Protect from light.

Keep in a safe place out of the reach of children.

Do not use after the expiry date.

## **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](http://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](http://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 care professionals can be obtained from:

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