

GONAL-*f*[®] RFF Redi-ject[™] (follitropin alfa injection)

INSTRUCTIONS FOR USE

For subcutaneous injection
Rx Only



300 IU/0.5 mL

450 IU/0.75 mL

900 IU/1.5 mL

Please see accompanying full Prescribing Information and Patient Information.

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INSTRUCTIONS FOR USE

**GONAL-f® RFF Redi-ject™ (gon-AL-eff ar-eff-eff REH-dee-jekt)
(follitropin alfa injection) for subcutaneous use**

300 International Units/0.5 mL pen

450 International Units/0.75 mL pen

900 International Units/1.5 mL pen

WELCOME

This flip chart contains information on how to use Gonal-f® RFF Redi-ject™ (follitropin alfa injection).

Gonal-f® RFF Redi-ject™ is an injection pen that delivers a prescription medicine containing follicle-stimulating hormone (FSH) used in infertile women to:

- help healthy ovaries develop (mature) and release an egg
- cause your ovaries to make multiple (more than 1) eggs as part of an Assisted Reproductive Technology (ART) program

Be sure that you read, understand, and carefully follow these instructions. Get familiar with the Gonal-f® RFF Redi-ject™ parts and features before you start using the Gonal-f® RFF Redi-ject™. Continue to refer to these instructions when using the Gonal-f® RFF Redi-ject™. You must receive training from a healthcare provider, such as a nurse or pharmacist, before using Gonal-f® RFF Redi-ject™. You will receive your own copy of these instructions to take home.

This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

If at any time you have questions or concerns, please contact your doctor's office or pharmacist.

IMPORTANT

- Gonal-f® RFF Redi-ject™ is for use **under the skin only** (subcutaneous)
- **Do not share** your Gonal-f® RFF Redi-ject™ and needles with another person, as this can cause an infection
- Gonal-f® RFF Redi-ject™ comes in **3 different dosage strengths**, and all the pens look the same. Your healthcare provider will prescribe the correct dose and pen for you and may change your dose during your treatment. Make sure you have the correct pen for your dose of Gonal-f® RFF Redi-ject™
- **You may need to use 2 pens for certain doses of Gonal-f® RFF Redi-ject™.** Your healthcare provider will tell you if you need to use 2 pens
- **Use your treatment diary while using Gonal-f® RFF Redi-ject™ to make sure you take the correct dose**, especially if you need to use 2 pens for your dose. Your healthcare provider should show you how to use your treatment diary

SUPPLIES YOU WILL NEED TO GIVE A GONAL-F® RFF REDI-JECT™ INJECTION

See Figure A.

- 1 Gonal-f® RFF Redi-ject™ pen. Your healthcare provider may prescribe 2 pens for your dose
- 1 new disposable needle. You will need 2 new needles if you use 2 pens for your dose
- 1 or 2 alcohol wipes
- 1 or 2 gauze pads
- Flat surface, such as a table
- Firm surface, such as a wall
- Sharps disposal container. See **Step 7** on page 21 for information on how to dispose of your used needles and pens
- Treatment diary, which comes with your pen, for recording your injections. See **Figure CC** and **Figure DD** at the end of these instructions for sample treatment diaries



Figure A

OVERVIEW

Steps you should follow to give a Gonal-f® RFF Redi-ject™ injection

Step 1. Preparing the pen

Step 2. Attaching the needle to the pen

Step 3. Removing large air bubbles from the pen

Step 4. Selecting the correct dose on the Gonal-f® RFF Redi-ject™

Step 5. Selecting the injection site and injecting your dose of Gonal-f® Redi-ject™

Step 6. What to do when your injection is completed

Step 7. Disposal of your used needles and pens

Step 8. Recording the Gonal-f® RFF Redi-ject™ injection in your treatment diary

Step 9. Storing your pen

STEP 1. PREPARING THE PEN

Note:

Your healthcare provider may prescribe a dose of Gonal-f® RFF Redi-ject™ that requires you to use **2 pens**. If you need to use 2 pens, follow the same instructions for both pens.

- Take the Gonal-f® RFF Redi-ject™ out of the refrigerator at least 30 minutes before you plan to inject your dose to allow it to warm to room temperature. Allowing the Gonal-f® RFF Redi-ject™ to warm to room temperature before injecting your dose will help make your injection more comfortable
- Open the carton by lifting the blue tab to open the top of the box. Look at the pen, and make sure you have the correct pen strength of Gonal-f® RFF Redi-ject™. Along with your pen, you should see needles in the carton. **See Figure B**
- Prepare a clean, flat surface, such as a table or countertop
- Gather all the supplies you need to give a Gonal-f® RFF Redi-ject™ injection
- Wash your hands well with soap and water. Dry your hands well
- Remove the pen and a new needle from the carton. Set aside the carton with extra needles. You will store the partially used pen in the carton later
- **Do not shake the pen.** Shaking the pen may cause air bubbles to appear in the reservoir. **See Figure C**
- Become familiar with the parts of your pen. **See Figure C.** The numbers you see in the dose display and the reservoir represent the number of international units (IU) of medicine

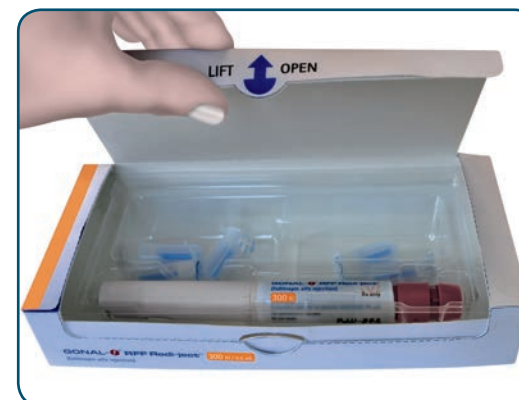


Figure B

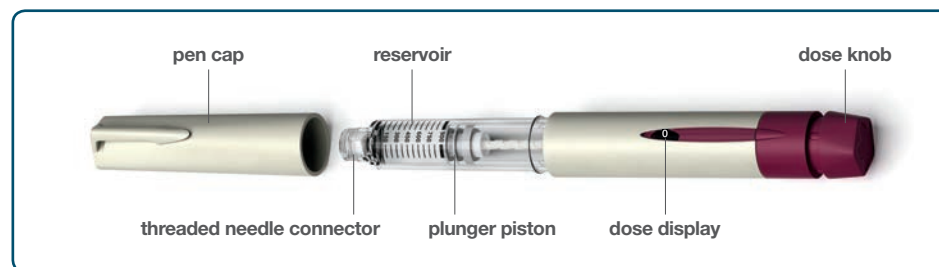


Figure C

STEP 1. PREPARING THE PEN (CONT.)

- Check the **expiration date** on the pen label. **See Figure D.** Do not use the pen if the date has expired. Get another pen with a date that has not expired from your healthcare provider or pharmacist

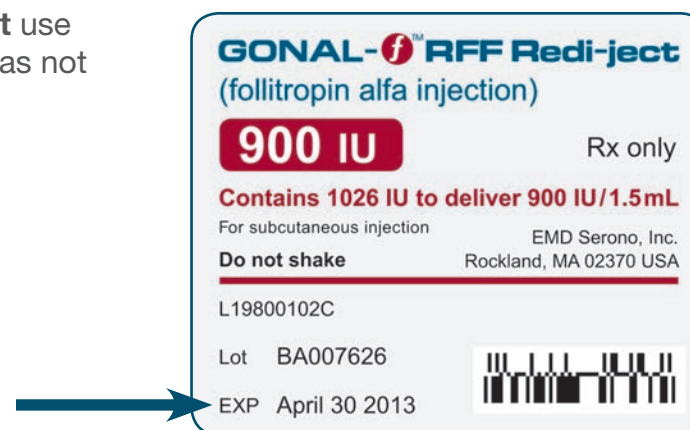


Figure D

- Hold the pen with one hand and pull off the pen cap with your other hand. Put the pen cap aside. You will place it back on the pen later. **See Figure E**

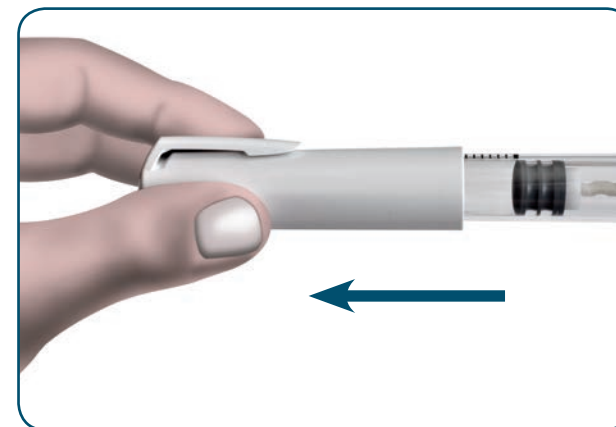


Figure E

STEP 1. PREPARING THE PEN (CONT.)

- Check the **reservoir** in the pen. **See Figure F.** There should be no cracks in the plastic window, and there should be liquid in the reservoir. The liquid should be clear and colorless with no particles. Get another pen if there are cracks in the reservoir, there is no liquid, or the liquid is not clear and colorless

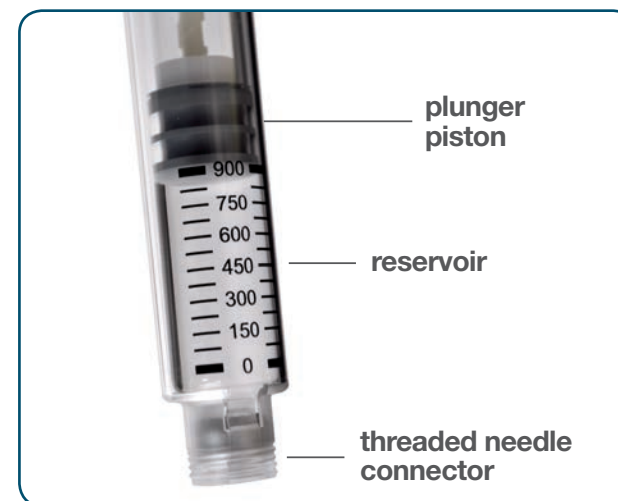


Figure F

- Check the **dose display** on the pen. If there is any number other than “0” on the dose display, set the dose display to “0.” To set the dose display, turn the dose knob in a counterclockwise direction until you see “0.” **See Figure G**

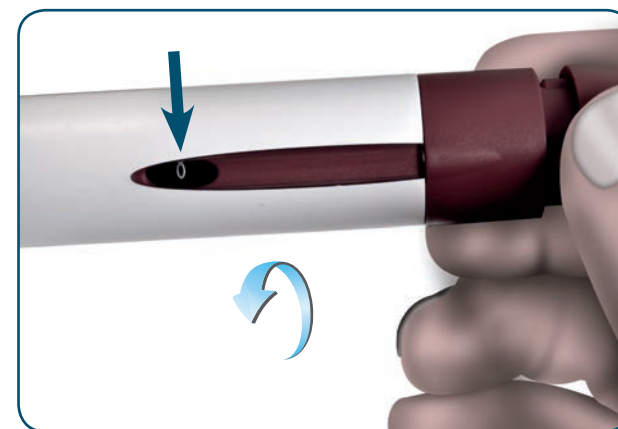


Figure G

STEP 2. ATTACHING THE NEEDLE TO THE PEN

- Pick up the new needle. See **Figure H** to become familiar with the parts of the needle you cannot easily see

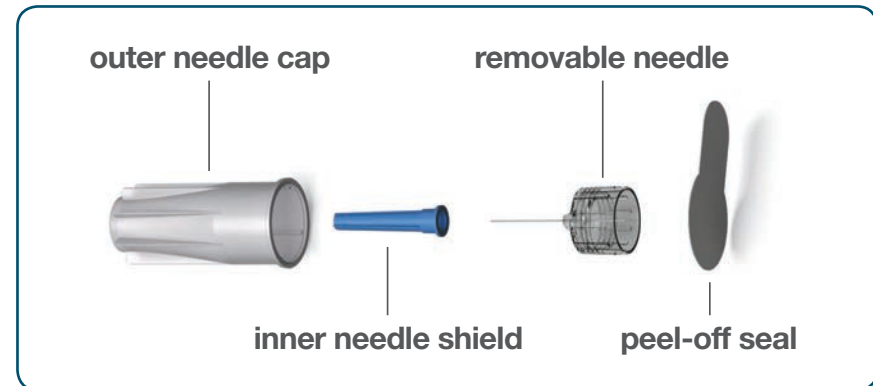


Figure H

- Remove the **peel-off seal** from the outer needle cap. See **Figure I**

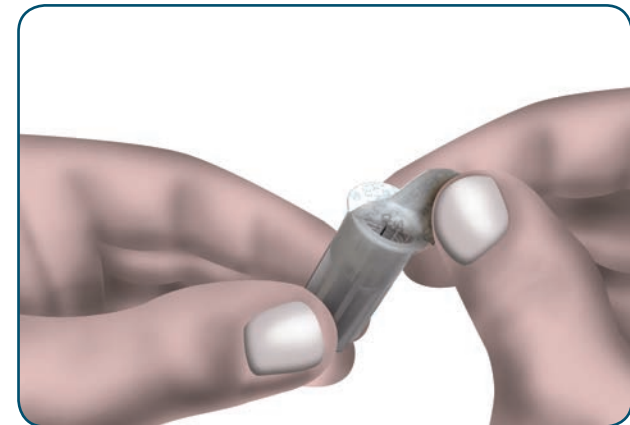


Figure I

STEP 2. ATTACHING THE NEEDLE TO THE PEN (CONT.)

- Hold the **outer needle cap** in one hand and the **pen** in your other hand. Place the needle on the end of the pen where you see threads. **See Figure J**
- Using some slight pressure, **screw the needle onto the pen in a counterclockwise direction** until you cannot turn the needle anymore. **See Figure J**

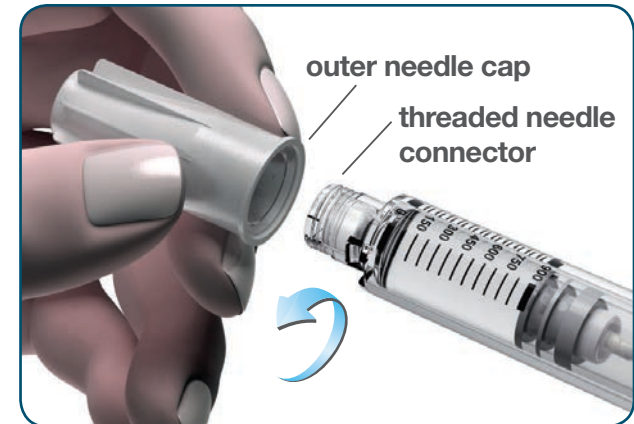


Figure J

- Gently remove the **outer needle cap** and place it on the table to use later. Leave the **blue inner needle shield** on the needle. **See Figure K**

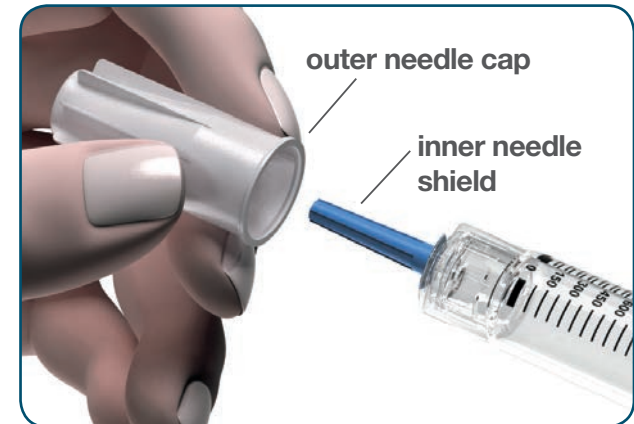


Figure K

STEP 3. REMOVING LARGE AIR BUBBLES FROM THE PEN

- Small air bubbles in the pen's reservoir do not need to be removed from the pen, **but large air bubbles in the pen's reservoir** must be removed.
See Figure L
- A large air bubble is a bubble that appears all the way across the top of the reservoir. If you do not see a large air bubble, go to Step 4 to select the correct dose of Gonal-f® RFF Redi-ject™ (follitropin alfa injection)

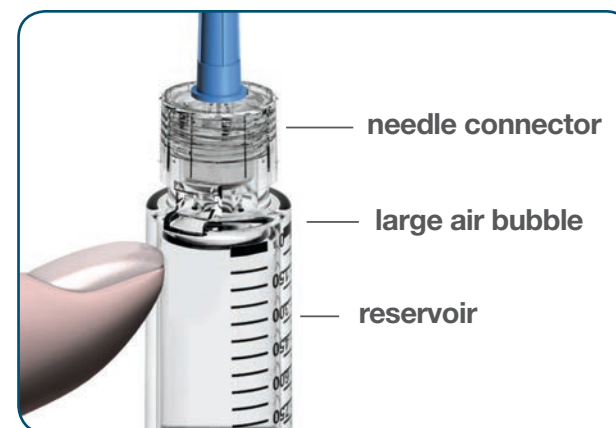


Figure L

- If you see a large air bubble, turn the **dose knob** in a clockwise direction until the dose display reads “•25,” meaning 25 IU. Only use 25 IU to remove air bubbles. **See Figure M**

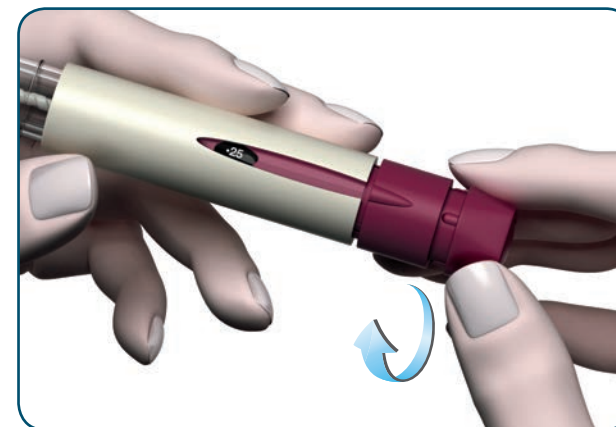


Figure M

STEP 3. REMOVING LARGE AIR BUBBLES FROM THE PEN (CONT.)

- Carefully remove the **blue inner needle shield** and throw it away. **Do not recap the needle with the blue inner needle shield.** See **Figure N**

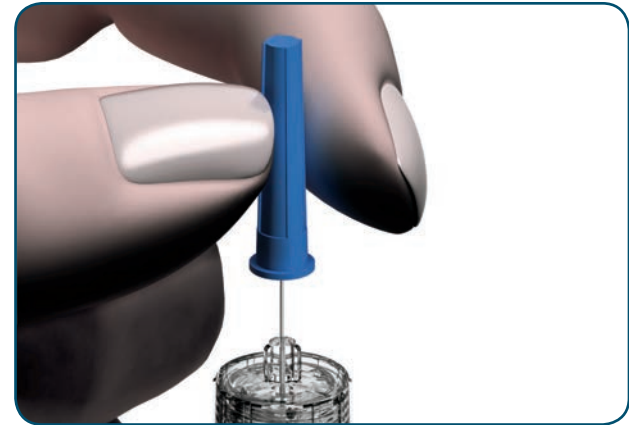


Figure N

- With the needle pointing up, tap the **reservoir** with your finger to allow any large air bubbles to rise to the top. See **Figure O**



Figure O

STEP 3. REMOVING LARGE AIR BUBBLES FROM THE PEN (CONT.)

- Holding the needle pointing up, slowly press the **dose knob** as far as it will go. Release the dose knob. **See Figure P**

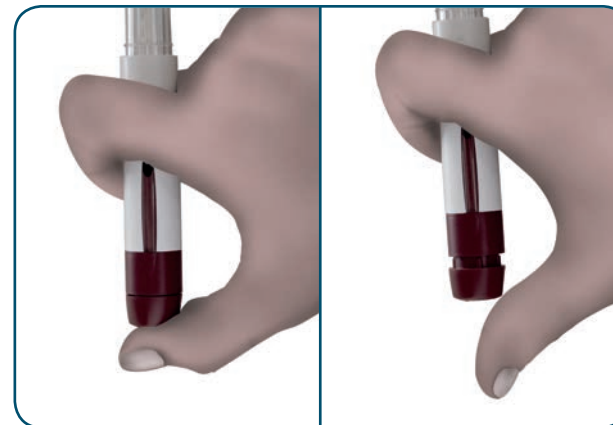


Figure P

- Find the **outer needle cap** and place on a flat surface
- Holding the pen in one hand, **slip the needle into the outer needle cap** without using your other hand. **See Figure Q**



Figure Q

STEP 3. REMOVING LARGE AIR BUBBLES FROM THE PEN (CONT.)

- Using 1 hand, push the capped needle against a surface that is firm but not slippery, such as a wall. Push until you hear a “click.” Pushing the capped needle against a wall will ensure the cap is firmly attached. See Figure R

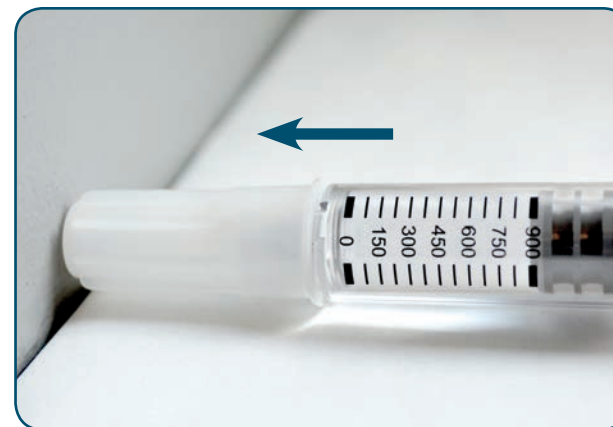


Figure R

- Turn the capped needle in a clockwise direction to unscrew the old capped needle from the pen. Replace with a new capped needle as described in Step 2. See Figure S

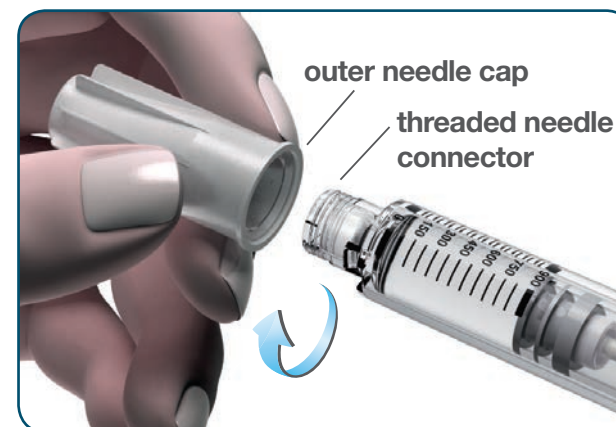


Figure S

STEP 4. SELECTING THE CORRECT DOSE ON THE GONAL-F® RFF REDI-JECT™

- Check your **treatment diary** if you are not sure what dose to use today. See **Figure CC** and **Figure DD** in **Step 8**. If you are unsure about your dose, call your healthcare provider
- Turn the dose knob in a clockwise direction until your prescribed dose of Gonal-f® RFF Redi-ject™ shows in the **dose display**. See **Figure T**

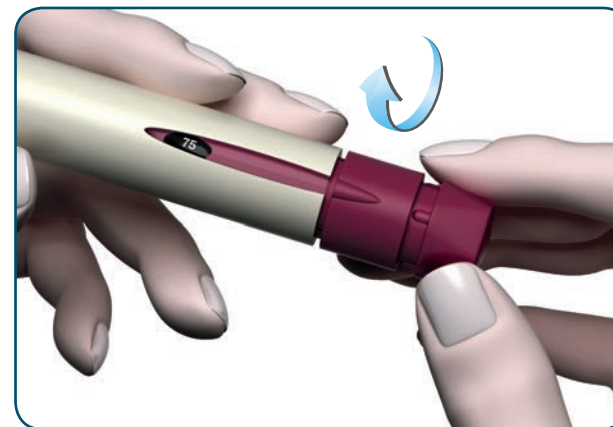


Figure T

- **Do not** push or pull the dose knob while you turn it. If you pass your dose, turn the dose knob back to the correct dose
- Look at the **dose display** on the pen in bright light, such as by a sunlit window or under a lamp. If there is glare on the pen, move the pen so you can clearly see the dose display
- The **dose display** in **Figure U** shows a dose of **150 IU** as an example: Your prescribed dose may be different

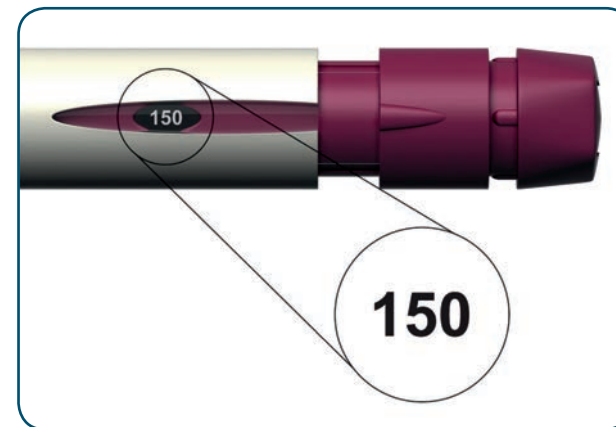


Figure U

STEP 5. SELECTING THE INJECTION SITE AND INJECTING YOUR DOSE OF GONAL-F® RFF REDI-JECT™

- Your healthcare provider should show you the injection sites to use around your **stomach** area. **See Figure V**
- Your healthcare provider may show you another area of your body to use for your injections if you cannot use your stomach
- **Use a different site** each time you inject yourself to reduce the chance of skin problems, such as redness and irritation

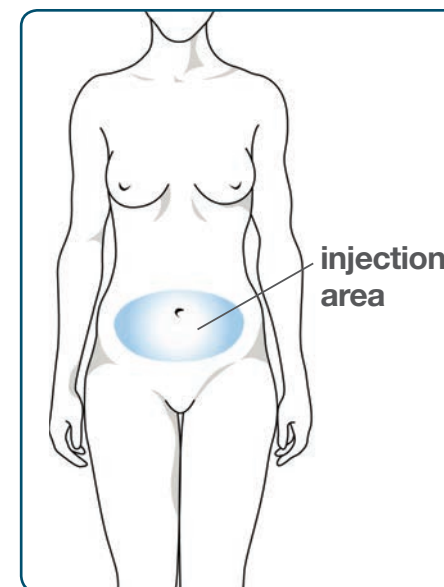


Figure V

- Select your injection site, and wipe the skin with an **alcohol wipes** as your healthcare provider showed you
- Pick up the pen. Make sure the dose on the **dose display** matches your prescribed dose. If the dose does not match your prescribed dose, adjust to the correct dose. **See Step 4**
- Carefully remove the **blue inner needle shield**, and throw it away. **Do not recap the needle with the blue inner needle shield.** **See Figure W**

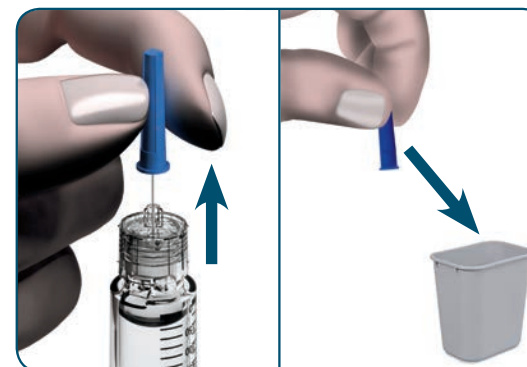


Figure W

STEP 5. SELECTING THE INJECTION SITE AND INJECTING YOUR DOSE OF GONAL-F® RFF REDI-JECT™ (CONT.)

- Hold the pen at a 90° angle, and push the needle into your skin. See Figure X.

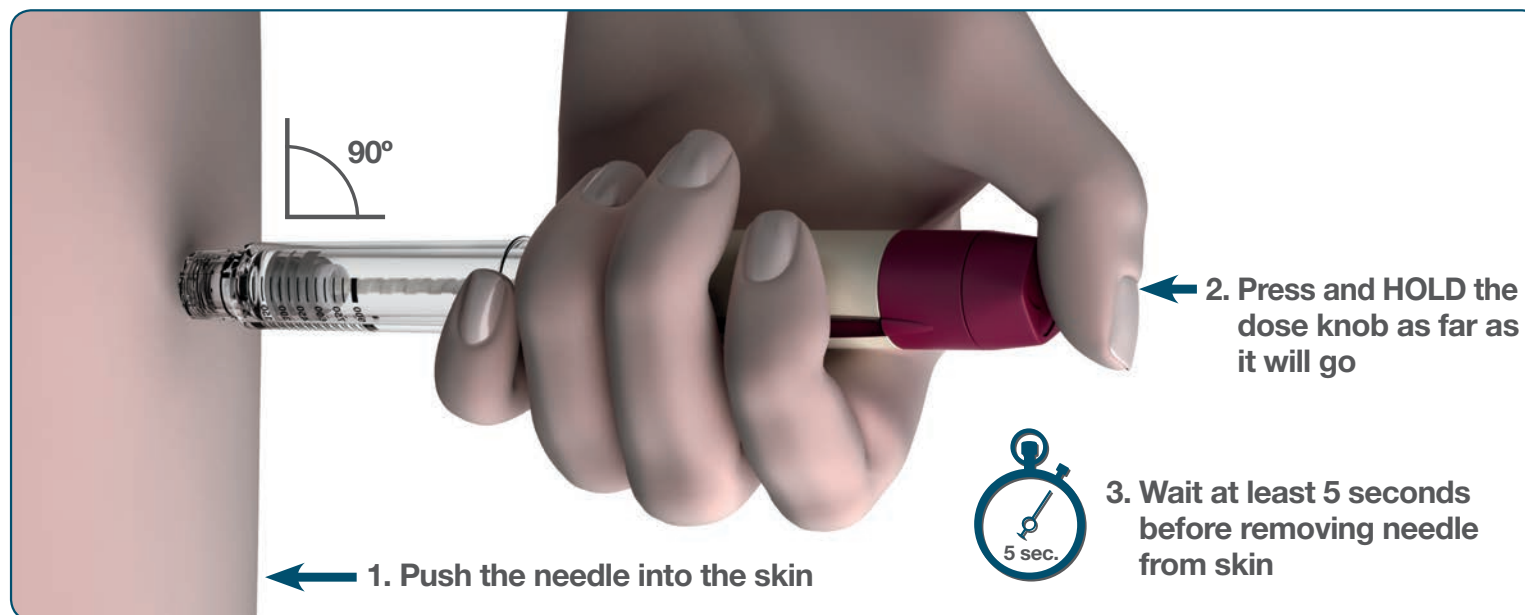


Figure X

- Press down on the **dose knob** with your thumb and hold the dose knob down as far as it will go to complete the full injection. See Figure X
- Wait at least **5 seconds** before removing the needle from the skin to make sure you receive your full dose
- Carefully **remove the needle** from your skin and put the pen on the table
- Hold a **gauze pad** firmly on your injection site for a few seconds to make sure the medicine does not leak out

STEP 6. WHAT TO DO WHEN YOUR INJECTION IS COMPLETED

- **Do not recap the needle.** Recapping a needle can lead to a needle-stick injury. Remove the needle from the pen after each injection
- Find the **outer needle cap** and place on a flat surface
- Holding the pen in one hand, **slip the needle into the outer needle cap without using your other hand.** See Figure Y

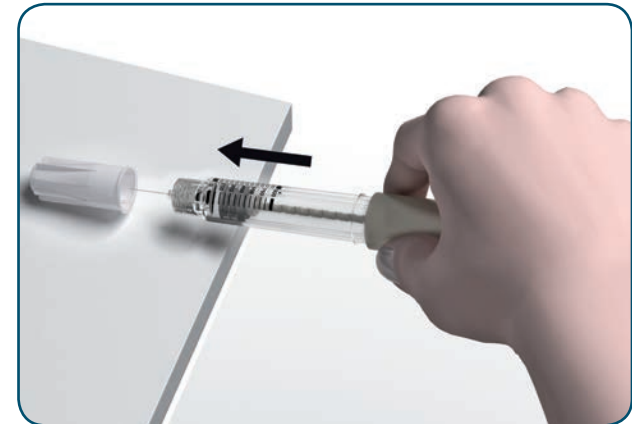


Figure Y

- **With one hand, push the capped needle against a surface that is firm but not slippery, such as a wall. Push until you hear a “click.”** Pushing the capped needle against a wall will make sure the cap is firmly attached. See Figure Z

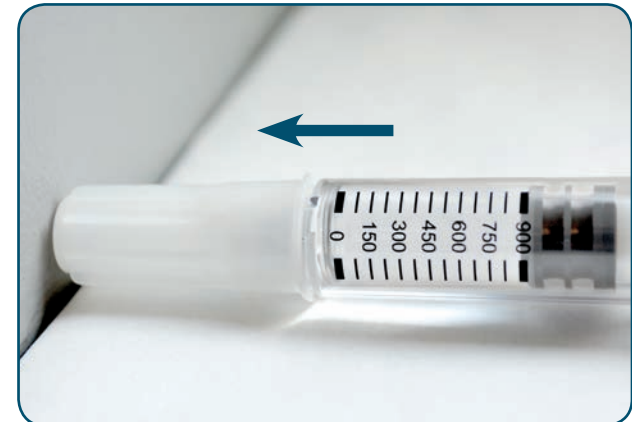


Figure Z

STEP 6. WHAT TO DO WHEN YOUR INJECTION IS COMPLETED (CONT.)

- Turn the capped needle in a clockwise direction to unscrew the needle from the pen. See **Figure AA**

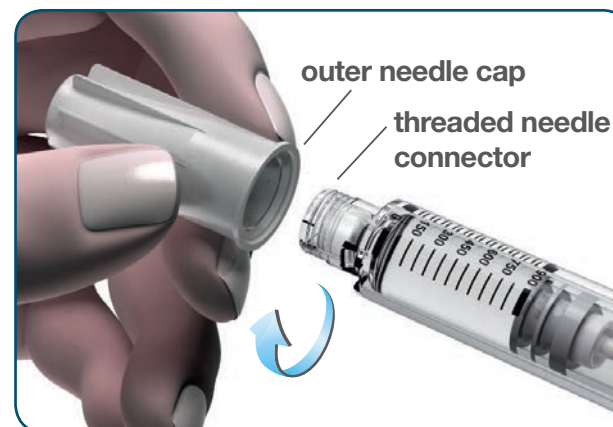


Figure AA

- Find the **pen cap** and push directly onto the end of the pen. The pen cap will not fit over a used needle. See **Figure BB**
- If there is medicine left in your pen, **go to Step 9** for storage information. If there is no medicine left in your pen, **go to Step 7** for disposal information

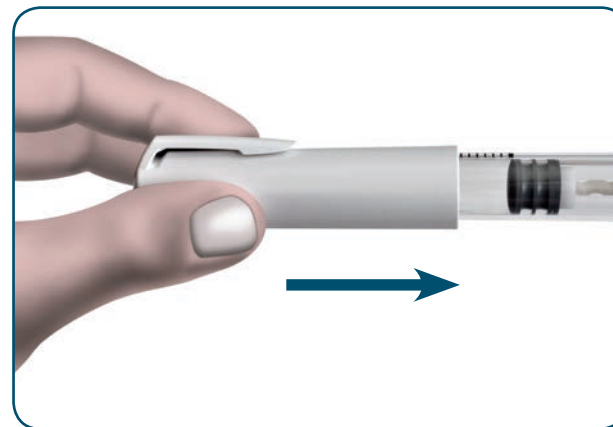


Figure BB

STEP 7. DISPOSAL OF YOUR USED NEEDLES AND PENS

- Put your used needles in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose needles and pens in your household trash**
- If you do not have an FDA-cleared sharps disposal container, you may use a household container that is: made of a heavy-duty plastic; can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out; upright and stable during use; leak-resistant; and properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and pens
- For more information about safe sharps disposal and for specific information about sharps disposal in the state in which you live, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container

STEP 8. RECORDING THE GONAL-F® RFF REDI-JECT™ INJECTION IN YOUR TREATMENT DIARY

- Unfold your treatment diary
- If your healthcare provider prescribed a dose of Gonal-f® RFF Redi-ject™ that is smaller than or the same size as the pen size you were given, **see Figure CC**
- If your healthcare provider prescribed a dose of Gonal-f® RFF Redi-ject™ that is larger than the pen size you were given, you will need to use 2 pens. **See Figure DD** on page 23

Sample treatment diary entry for using 1 pen:

- **For example**, a 375-IU dose (column 5) given with the 450-IU pen (column 4)

Treatment Day using a 450-IU Gonal-f® RFF Redi-ject™ to give 375 IU

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8
Today's Treatment Day Is:	Today's Date Is:	Treatment Time Is:	Pen Used (300 IU, 450 IU, or 900 IU):	Dose Display Set to Today's Prescribed Dose of:	After Injection, Dose Display Reads "0." See Figure G in Step 1. (Yes/No)	If Column 6 Answer Is "No," Dose to Set for Second Injection Is:	Notes
1	July 6, 2013	8:50 PM	450	375	yes		Injection given.

Figure CC

STEP 8. RECORDING THE GONAL-F® RFF REDI-JECT™ INJECTION IN YOUR TREATMENT DIARY (CONT.)

Sample treatment diary entry for using 2 pens:

- **For example**, a 375-IU prescribed dose using two 300-IU pens
 - Change your treatment diary entry (column 5) if needed
 - Add another treatment row for your second injection on that same treatment day

Treatment Day using two 300-IU Gonal-f® RFF Redi-ject™ pens to give 375 IU

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6	Column 7	Column 8
Today's Treatment Day Is:	Today's Date Is:	Treatment Time Is:	Pen Used (300 IU, 450 IU, or 900 IU):	Dose Display Set to Today's Prescribed Dose of:	After Injection, Dose Display Reads "0" See Figure G in Step 1. (Yes/No)	If Column 6 Answer Is "No," Dose to Set for Second Injection Is:	Notes
1	July 6, 2013	8:50 PM	300	300	yes		Nurse instructed 375 IU for today's dose, so need to use 2 pens. 300 IU used from the first pen. Injection given.
1	July 6, 2013	8:50 PM	300	75	yes		75 IU used from the second pen. Injection given, complete dose taken.

Figure DD

STEP 8. RECORDING THE GONAL-F® RFF REDI-JECT™ INJECTION IN YOUR TREATMENT DIARY (CONT.)

- **Note:** If you see a number other than “0” on the pen’s dose display after giving your injection, for example “75.” See Figure EE



Figure EE

- Enter “No” in **column 6** of your treatment diary. See Figure FF
- Enter the dose display reading in **column 7**, “75.” This is the setting to dial for the **new pen** to complete your prescribed dose for the day. See Figure FF

Column 6	Column 7	Column 8
After Injection, Dose Display Reads “0.” See Figure G in Step 1. (Yes/No)	If Column 6 Answer Is “No,” Dose to Set for Second Injection Is:	Notes
No	75	Need new pen to finish.

Figure FF

- You will need a **new pen** to complete your prescribed dose for the day
- To remove the used needle, go to **Step 6**
- Then go to **Step 1 through Step 5** to complete your dose for the day with the **new pen**
- Record your dose of Gonalf® RFF Redi-ject™ in your treatment diary where shown

STEP 9. STORING YOUR PEN

- **Before you use your pen for the first time**, store your pen:
 - In the refrigerator between 36°F to 46°F (2°C to 8°C) until the expiration date, or
 - Store your pen at room temperature between 68°F to 77°F (20°C to 25°C) for up to 3 months or until the expiration date, whichever comes first
- **After you use your pen and there is still medicine left**, store your pen in the refrigerator or at room temperature for up to 28 days
- Throw away any unused Gonal-f® RFF Redi-ject™ after 28 days
- Store your Gonal-f® RFF Redi-ject™ with the pen cap on in a safe place
- Store the Gonal-f® RFF Redi-ject™ away from light
- Do not freeze Gonal-f® RFF Redi-ject™
- Keep Gonal-f® RFF Redi-ject™ and all other medicines out of the reach of children

These instructions for use have been approved by the US Food and Drug Administration

For more information, go to www.fertilitylifelines.com or call 1-866-538-7879.

Approved: October 2013

Please see accompanying full Prescribing Information and Patient Information.



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GONAL-^f RFF Redi-jectTM
(follitropin alfa injection)

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Darmstadt, Germany

