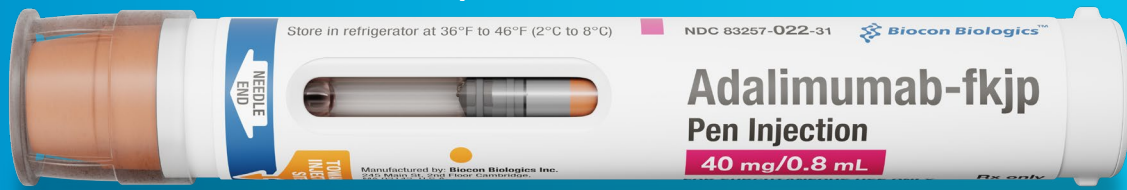


Instructions for Use

Adalimumab-fkjp Injection



for subcutaneous use 40 mg/0.8 mL

Single-Dose Prefilled Pen

INSTRUCTIONS FOR USE:

Adalimumab-fkjp Pen Injection 40 mg/0.8 mL Single-Dose Pen

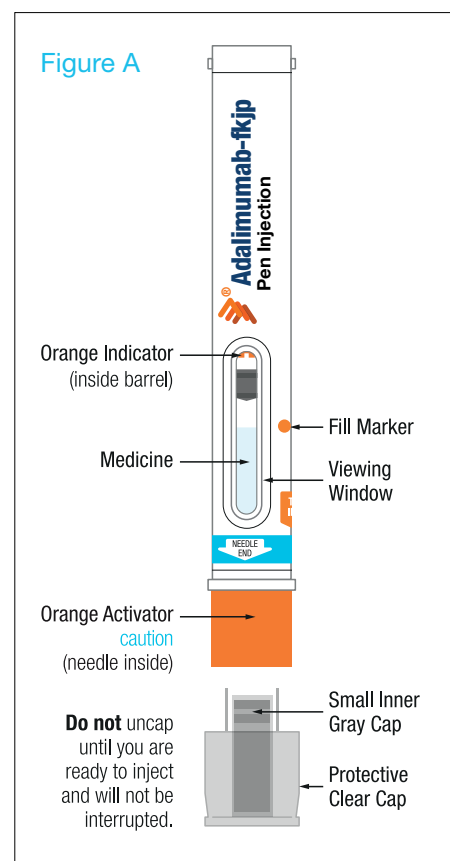
IMPORTANT INFORMATION:

- **Do not** try to inject Adalimumab-fkjp yourself until you have been shown the right way to give the injections and have read and understand this Instructions for Use.
- If your healthcare provider decides that you or a caregiver may be able to give your injections of Adalimumab-fkjp injection at home, you should receive training on the right way to prepare and inject Adalimumab-fkjp injection.
- There will be a “click” during your injections. You should practice injecting Adalimumab-fkjp injection with your healthcare provider so that you are not startled by this “click” when you start giving yourself injections at home.
- It is important that you read, understand, and follow these instructions so that you inject Adalimumab-fkjp injection the right way. It is also important to talk to your healthcare provider to be sure you understand your Adalimumab-fkjp injection dosing instructions.
- To help you remember when to inject Adalimumab-fkjp injection, you can mark your calendar ahead of time.
- Call your healthcare provider if you or your caregiver have any questions about the right way to inject Adalimumab-fkjp injection.

- Each Adalimumab-fkjp Pen can only be used one time. Throw the used Pen away (**See How should I throw away (dispose of) the used Adalimumab-fkjp Pen**) after one dose, even if there is still medicine left in it. Do not reuse your Adalimumab-fkjp Pen.

For Questions or Assistance, Call Biocon Biologics at 1-833-986-1468

The figure below shows what the Adalimumab-fkjp Pen looks like. See Figure A.



Step 1. Gather the Supplies for Your Injection

- **Take your Adalimumab-fkjp Pen out of the refrigerator 15 to 30 minutes** before injecting to allow the liquid to reach room temperature.
 - **Do not** warm Adalimumab-fkjp injection in any other way (for example, **do not** warm it in a microwave or in hot water).
 - **Do not use Adalimumab-fkjp injection if it has been frozen, even if it has been thawed.**
 - **Do not** put the Adalimumab-fkjp injection Pen back in the refrigerator after reaching room temperature.
- **Do not** uncap your Adalimumab-fkjp Pen until you are ready to inject and will not be interrupted.

You will need the following supplies for each injection of Adalimumab-fkjp injection.

- 1 Adalimumab-fkjp Pen (See Figure A)
- 1 alcohol swab
- 1 cotton ball or gauze pad (not included in your Adalimumab-fkjp injection carton)
- Puncture-resistant sharps disposal container for Adalimumab-fkjp Pen disposal (not included in your Adalimumab-fkjp injection carton). See the **“How should I throw away (dispose of) the used Adalimumab-fkjp Pen?”** section at the end of this Instructions for Use.

If you do not have all the supplies you need to give yourself an injection, go to a pharmacy or call your pharmacist.

Find a clean, flat surface to place the supplies on.

Step 2. Check the Carton, Dose Tray and Adalimumab-fkjp Pen

- Make sure the name Adalimumab-fkjp injection appears on the carton, dose tray, and Adalimumab-fkjp Pen label.
- Check the seals on the top or bottom of the carton to make sure they are not broken or missing.

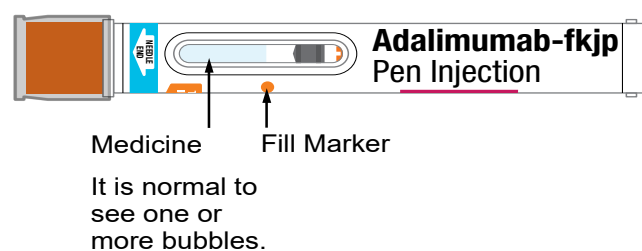
- Check the expiration date on the carton, dose tray, and Adalimumab-fkjp Pen.
- **Do not use** the Adalimumab-fkjp Pen and **call** your healthcare provider or pharmacist if:
 - you drop or crush your Adalimumab-fkjp Pen.
 - the seals on the top or bottom of the carton are broken or missing.
 - the expiration date on the carton, dose tray, and Pen has passed.
 - The Adalimumab-fkjp Pen has been frozen or left in direct sunlight.
 - Adalimumab-fkjp injection has been kept at room temperature for longer than **14 days** or Adalimumab-fkjp injection has been stored above 77°F (25°C).
 - the liquid in the Adalimumab-fkjp Pen is cloudy, discolored or has flakes or particles in it.

See the **“How should I store Adalimumab-fkjp injection?”** section at the end of this Instructions for Use.

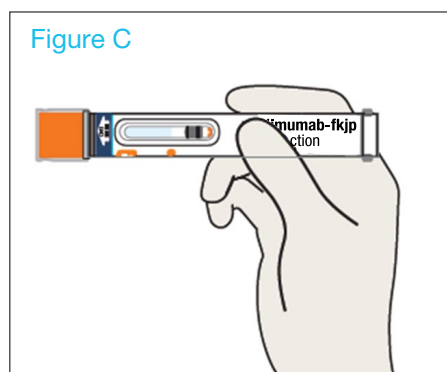
Check the fluid level in the Pen:

- Hold the Pen with the protective clear cap covering the orange activator pointed down. (See Figure B).
- Make sure the amount of liquid in the Pen is at the fill line or close to the fill line seen through the window. You may need to shake gently to see the liquid. This is the full dose of Adalimumab-fkjp injection that you will inject. (See Figure B).
- If the Pen does not have the full amount of liquid, **do not use that Pen**. Call your pharmacist.

Figure B



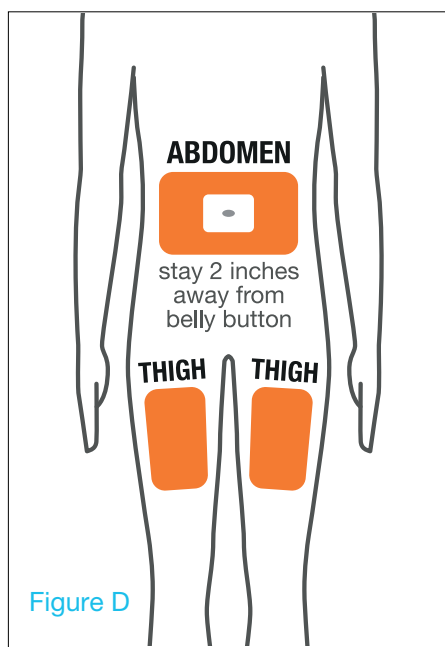
- Turn the Pen and hold with the protective clear cap covering the orange activator pointed side ways. (See Figure C).



- **Check the solution** through the windows on the side of the Pen to make sure the liquid is clear and colorless to pale brownish-yellow.
- **Do not use** your Adalimumab-fkjp Pen if the liquid is cloudy, discolored, or if it has flakes or particles in it. Call your pharmacist.
- It is normal to see one or more bubbles in the window

Step 3. Choose the Injection Site

- Wash your hands with soap and water and dry well.
- Choose an injection site on:
 - the front of your thighs or
 - your lower abdomen (belly). If you choose your abdomen, do not use the area 2 inches around your belly button (navel). (See Figure D).



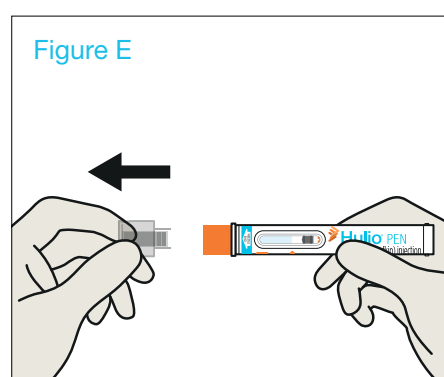
- Choose a different site (rotate) each time you give yourself an injection. Each new injection should be given at least 1 inch from a site you used before.
- **Do not** inject Adalimumab-fkjp injection into skin that is:
 - sore (tender)
 - bruised
 - red
 - hard
 - Scarred or where you have stretch marks
 - If you have psoriasis, **do not** inject directly into any raised, thick, red or scaly skin patches or lesions on your skin.
 - **Do not** inject through your clothes.

Step 4: Prepare the Injection Site

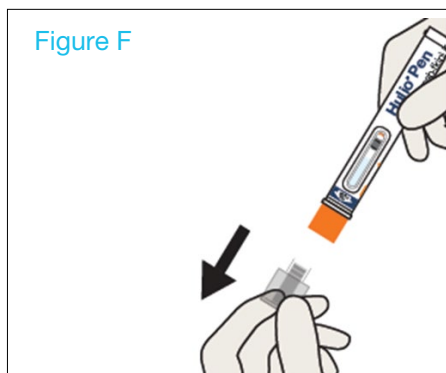
- Wipe the injection site with an alcohol prep (swab) using a circular motion.
- **Do not** touch this area again before giving the injection.
- Allow the skin to dry before injecting.
Do not fan or blow on the clean area.

Step 5. Prepare the Adalimumab-fkjp Pen

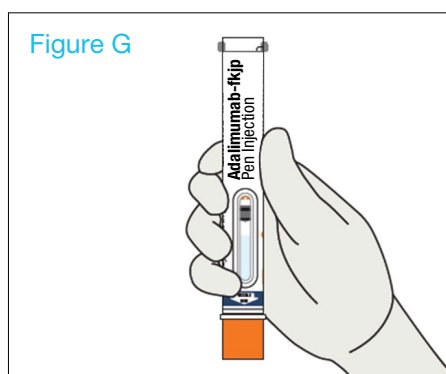
- **Do not** remove the protective clear cap until right before your injection.
- Hold the middle of the Pen (white body) with one hand so that you are not touching the protective clear cap. Turn the Pen so that the orange activator end is pointing down. See (Figure E).



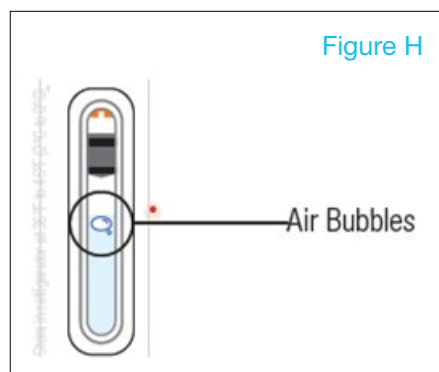
With your other hand, pull the protective clear cap straight off (**do not** twist the cap). Make sure the small needle cover of the syringe has come off with the protective clear cap. (See Figure F).



- **Important:** **Do not** put the protective clear cap back on. It may damage the needle.
- Throw away the protective clear cap.
- The orange activator which covers the needle is where the needle comes out. The needle can now be seen.
- **Caution:**
 - **Never put your thumb, fingers, or hand over the orange activator after the protective clear cap is removed.**
 - Never press or push the orange activator with your thumb, fingers, or hand.
 - If accidental injection to your fingers or hands happens, apply first-aid and either call your healthcare provider or go to the nearest hospital emergency room if needed.
 - **Do not** touch the needle with your fingers or let the needle touch anything.
- You may see a few drops of liquid. Turn the Pen so the white end is pointed up. (See Figure G).
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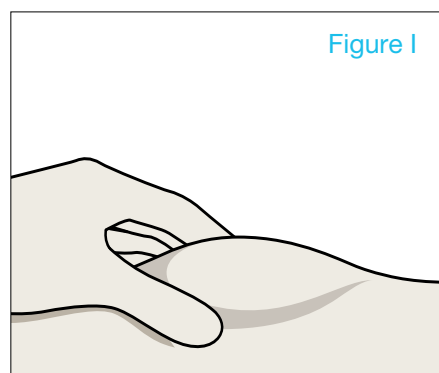


- Hold the Pen so that you can see the window. (See Figure H). It is normal to see one or more bubbles in the window.

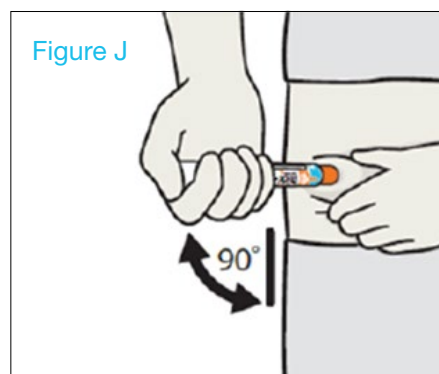


Step 6. Position the Pen

- **Squeeze** the area of the cleaned skin and hold it firmly until the injection is complete. (See Figure I). You will inject into this raised area of skin.

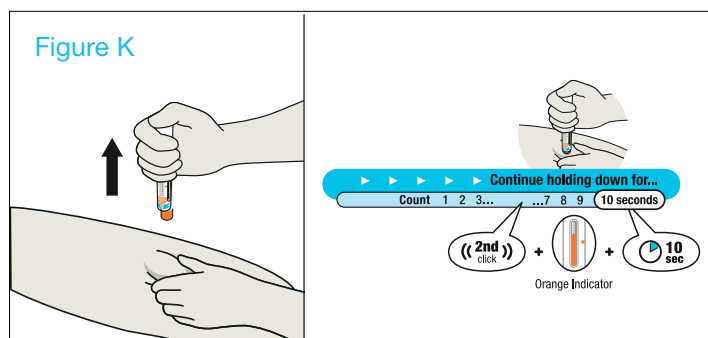


- Place the orange activator end of the Pen straight (**at a 90° angle**) and flat against the raised area of your skin that you are squeezing.
- Place the Pen so that it will not inject the needle into your fingers that are holding the raised skin. (See Figure J).

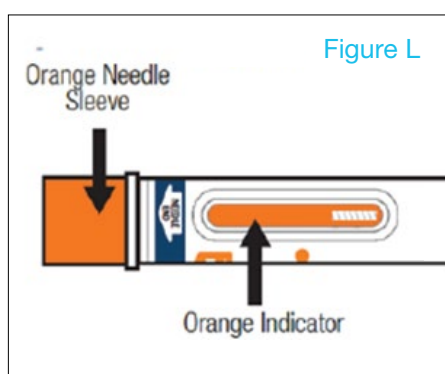


Step 7. Inject Adalimumab-fkjp injection

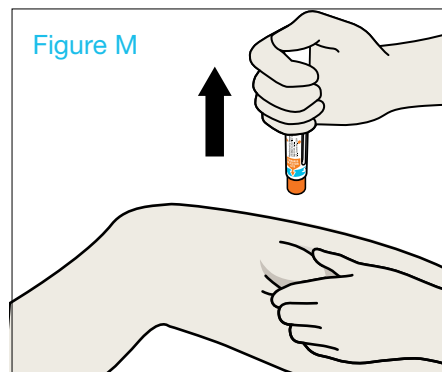
- **It is important that you firmly push the Pen down** all the way against the injection site to begin the injection. Try not to cover the window. (See Figure K).
- **Do not move, twist, or rotate the Pen during the injection.**



- **Keep pushing down** to prevent the Pen from moving away from the skin during the injection.
- You will hear a loud 'click' when the orange activator is pressed down against the injection site. The loud click means the start of the injection.
- Continue to push the Pen against your squeezed, raised skin until all the medicine is injected. This can take up to 10 seconds, so count slowly to ten. Keep pushing the Pen against the squeezed, raised skin of your injection site for the whole time so you get the full dose of medicine.
- You will know that the injection has finished when:
 - A 2nd 'Click' was heard, and
 - Orange indicator has stopped moving and completely blocked the viewing window (See Figure L)
 - 10 seconds has passed.
- Make sure all 3 of these have happened to make certain all the medicine was delivered. If the needle did not retract or you **do not** think you received the full dose, contact your healthcare provider for help.



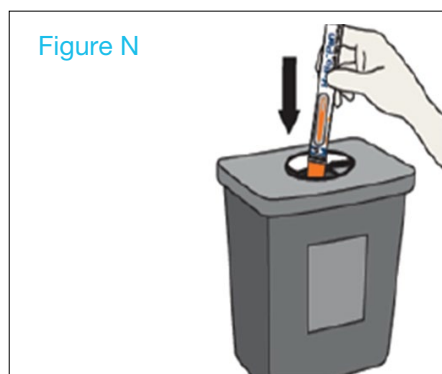
- When the injection is finished, slowly pull the Pen from your skin. The white needle sleeve will move to cover the needle tip. (See Figure M).



- **Do not** touch the needle. The white needle sleeve is there to prevent you from touching the needle.
- If the needle did not retract or you **do not** think you received the full dose, contact your healthcare provider for help.
- There may be a small amount of liquid on the injection site. This is normal.
- Press a cotton ball or gauze pad over the injection site and hold it for 10 seconds. **Do not** rub the injection site. You may have slight bleeding. This is normal.

Step 8. Throw away (dispose of) your used Adalimumab-fkjp Pen in a sharps disposal container right away after use. See the section "How should I throw away (dispose of) the used Adalimumab-fkjp Pen?"

- Put your Pen in an FDA-cleared sharps disposal container right away after use. (See Figure N). **Do not throw away the Pen in your household trash.**
- **Do not** try to touch the needle. The orange needle sleeve is there to prevent you from touching the needle.



- If you do not have a 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 syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at:
<http://www.fda.gov/safesharpsdisposal>.
- For the safety and health of you and others, never re-use your Adalimumab-fkjp Pens.
- The used alcohol pads, cotton balls, dose trays and packaging may be placed in your household trash.
- **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.**
- **Always keep the sharps container out of the reach of children.**

Keep a record of the dates and location of your injection sites. To help you remember when to take Adalimumab-fkjp injection, you can mark your calendar ahead of time.

Injection Diary

Date	Injection Site Used

How should I Store Adalimumab-fkjp injection?

- Store Adalimumab-fkjp injection in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Store Adalimumab-fkjp injection in the original carton until use to protect it from light.
- **Do not** freeze Adalimumab-fkjp injection.
- If needed, for example when you are traveling, you may also store Adalimumab-fkjp injection at room temperature up to 77°F (25°C) for up to **14** days.
- Throw away Adalimumab-fkjp injection if it has been kept at room temperature and not been used within **14** days.
- **Do not** store Adalimumab-fkjp injection in extreme heat or cold, such as a hot car, or a freezing car overnight.
- Keep Adalimumab-fkjp injection, injection supplies, and all other medicines out of the reach of children.

This Instructions for Use has been approved by the US Food and Drug Administration.

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