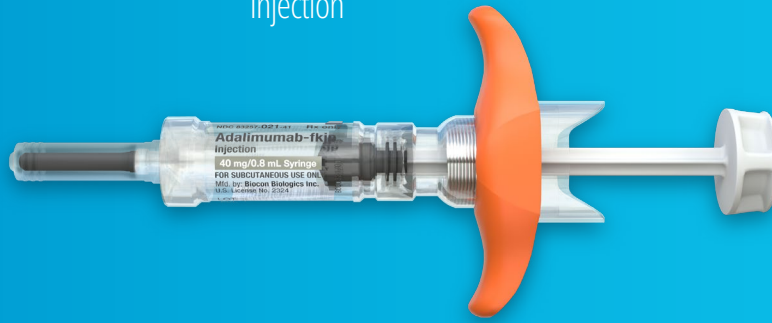


Instructions for Use

Adalimumab-fkjp Injection



for subcutaneous use 20 mg/0.4 mL and 40 mg/0.8 mL

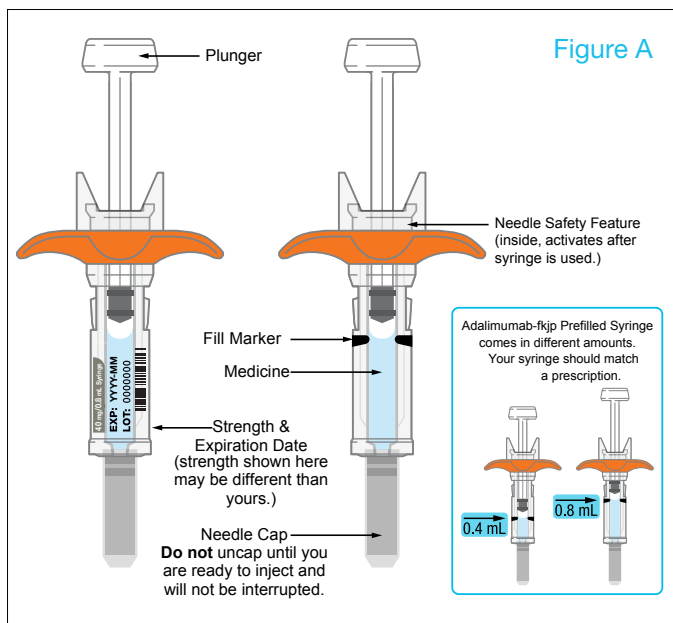
Single-Dose Prefilled Syringe

Read these instructions carefully before using your Syringe.

This information does not replace talking to your doctor about your medical condition and your treatment.

IMPORTANT INFORMATION:

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



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

The figure shows what a prefilled syringe looks like. (See Figure A)

Step 1. Gather the Supplies for Your Injection

- **Take your Adalimumab-fkjp prefilled syringe 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 Adalimumab-fkjp injection back in the refrigerator after reaching room temperature.**
- **Do not** uncap your Adalimumab-fkjp Prefilled Syringe 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 Prefilled Syringe (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 prefilled syringe disposal (not included in your Adalimumab-fkjp injection carton). See **“How should I throw away (dispose of) the used prefilled syringes and needles?”** 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 prefilled Syringe

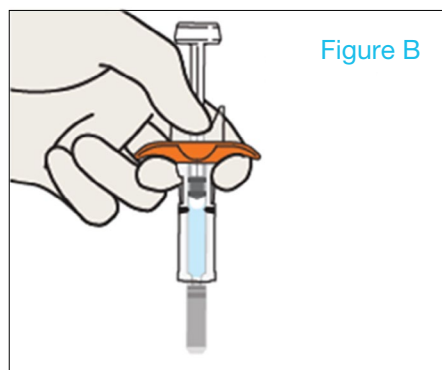
- Make sure the name Adalimumab-fkjp injection appears on the dose tray and prefilled syringe label.
- Check the seals on the top or bottom of the carton to make sure they are not broken or missing.
- Check the expiration date on the carton, dose tray, and Adalimumab-fkjp Prefilled Syringe.
- **Do not** use the Adalimumab-fkjp Prefilled Syringe and **call** your healthcare provider or pharmacist if:
 - you drop or crush your Adalimumab-fkjp Prefilled Syringe.

- the seals on the top or bottom of the carton are broken or missing.
- the expiration date on the carton, dose tray, and Adalimumab-fkjp Prefilled Syringe have passed.
- the prefilled syringe 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 prefilled syringe is cloudy, discolored or has flakes or particles in it.

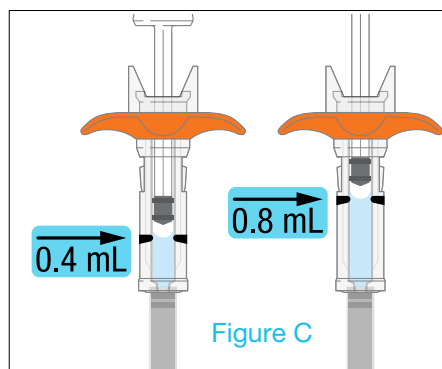
See the **“How should I store Adalimumab-fkjp injection?”** section at the end of this Instructions for Use.

Check the fluid level in the syringe:

- Hold the syringe with the covered needle pointing down. (See Figure B).



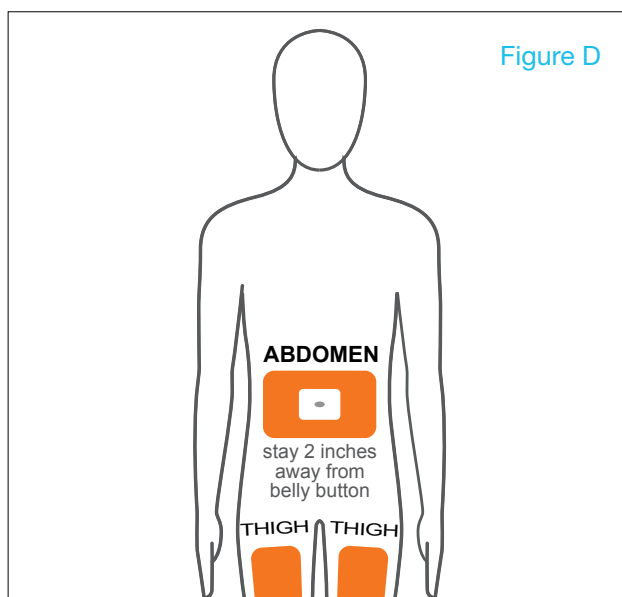
- Hold the syringe at eye level. Look closely to make sure that the amount of liquid in the syringe is the to the:
 - 0.8 mL line for the 40 mg prefilled syringe. (See Figure C).
 - 0.4 mL line for the 20 mg prefilled syringe. (See Figure C)



- You may need to shake gently to see liquid.
- The top of the liquid may be curved. If the syringe does not have the correct amount of liquid, **do not use that syringe**. Call your pharmacist.

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.

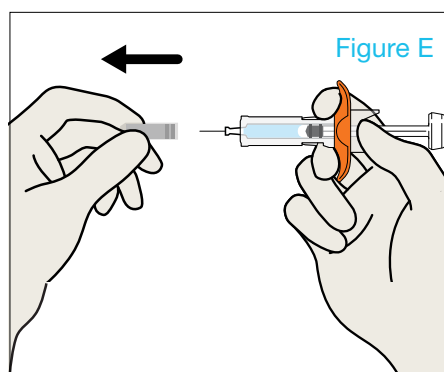
Step 4. Prepare the Injection Site

- 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 Prefilled Syringe and Needle

- Do not remove the needle cover until right before your injection.
- Hold the syringe in one hand. With the other hand gently remove the needle cover. (See Figure E).

Throw away the needle cover.

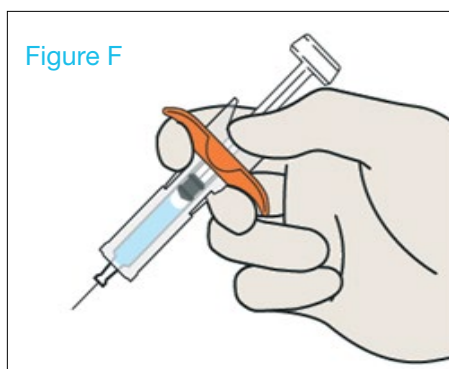


Important:

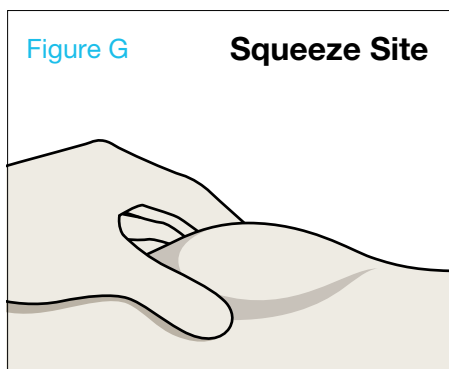
- **Do not** touch the needle with your fingers or let the needle touch anything.
- **Do not** replace the needle cover.
- **Do not** remove air bubbles.
- **Do not** use the syringe if dropped after removing the needle cover.
- You may see a drop of liquid at the end of the needle. This is normal.

Step 6. Position the Syringe

- Hold the body of the prefilled syringe in one hand between the thumb and index finger. Hold the syringe in your hand like a pencil. (See Figure F).

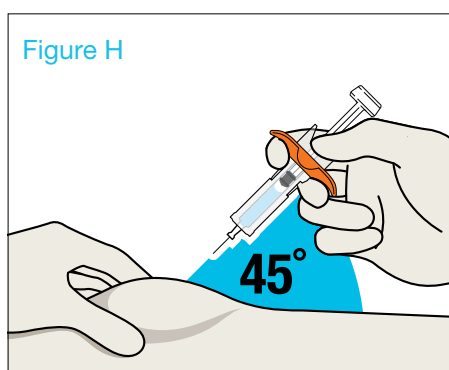


- **Do not** pull back on the plunger at any time.
- With your other hand, gently squeeze the area of the cleaned skin and hold it firmly. (See Figure G).



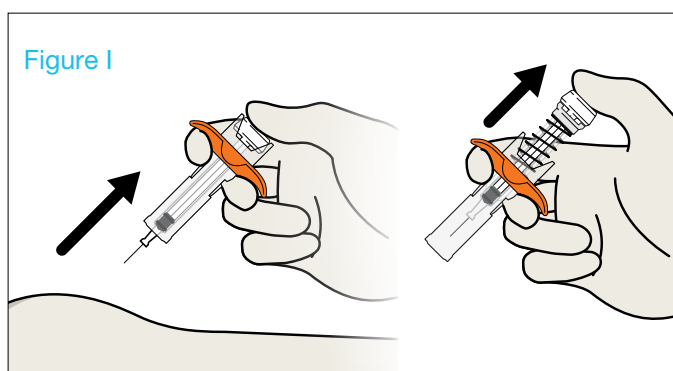
Step 7. Inject Adalimumab-fkjp injection

- Using a quick, dart-like motion, insert the needle into the squeezed skin at about a **45-degree angle**. (See Figure H).



- After the needle is in, let go of the skin.
- **Do not move, twist, or rotate the Syringe during the injection.**
- Slowly push the plunger all the way in until all the liquid is injected and the syringe is empty.

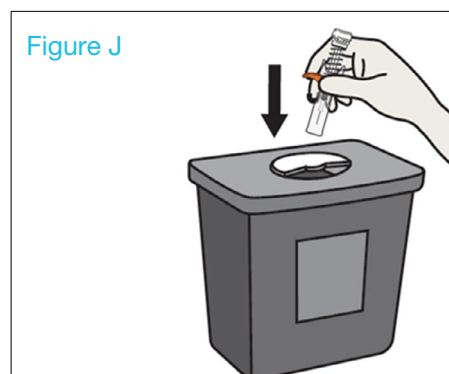
- If the plunger is not pressed all the way down the Needle Safety Feature will not activate afterwards to cover the needle
- **Do not** move, twist, or rotate the syringe during injection.
- Pull the needle out of the skin while keeping the syringe at the same angle, then release your thumb from the plunger.
- The needle will retract and the Needle Safety Feature will cover the needle. (See Figure I).



Caution: If the needle did not retract or you do not think you received the full dose, contact your healthcare provider for help.

- 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 Prefilled Syringe and needle in a sharps disposal container right away after use. (See Figure J).



“How should I throw away (dispose of) used prefilled syringes and needles?”

- Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. (See Figure J). **Do not throw away (dispose of) loose needles and syringes in your household trash.**
- **Do not** try to touch 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, needles and used syringes **must never** be re-used.
- 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 in the injection diary. 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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