

Instructions for Use

Welcome!

AMJEVITA™ is supplied as a single-dose prefilled syringe. Consult your doctor if you have any questions about your dose.

Your doctor has prescribed AMJEVITA prefilled syringe for your injections. If your doctor decides that you or a caregiver may be able to give your injections of AMJEVITA at home, you should receive training on the right way to prepare and inject AMJEVITA. Do not try to inject yourself until you have been shown the right way to give the injections by your doctor or nurse.

Please read all of the instructions before using the AMJEVITA prefilled syringe.

Call your doctor if you or your caregiver have any questions about the right way to inject AMJEVITA.

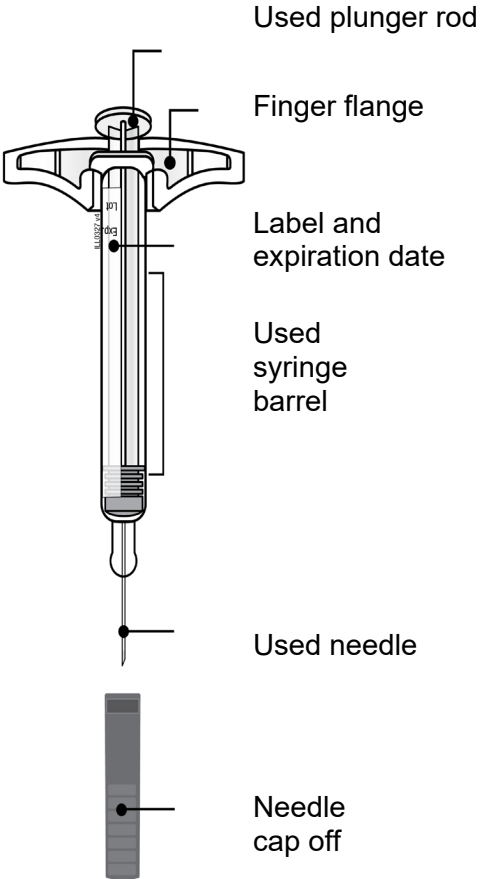
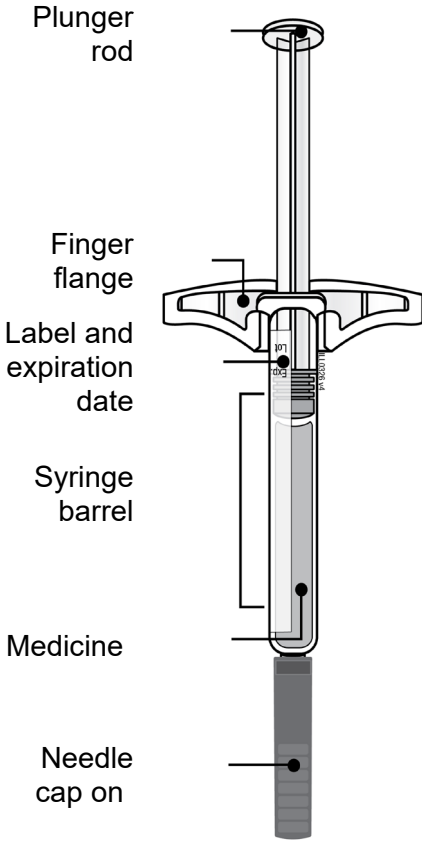
Instructions for Use
AMJEVITA™ (am-jeh-vee'-tah)
(adalimumab-atto)
injection, for subcutaneous use

Single-Dose Prefilled AMJEVITA Syringe

Guide to parts

Before use

After use



Important: The needle is covered by the needle cap before use.

Important

Before you use an AMJEVITA prefilled syringe, read this important information:

Storing your AMJEVITA prefilled syringes

- Keep the AMJEVITA prefilled syringe and all medicines out of the reach of children.
- Keep the AMJEVITA prefilled syringe in the original carton to protect from light or physical damage.
- The AMJEVITA prefilled syringe should be kept in the refrigerator at 36° F to 46° F (2° C to 8° C).
- If needed, you may store the AMJEVITA prefilled syringe at room temperature up to 77° F (25° C) for up to **14** days. Throw away AMJEVITA if it has been kept at room temperature and has not been used within **14** days.
- **Do not** store the AMJEVITA prefilled syringe in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.
- **Do not** freeze.

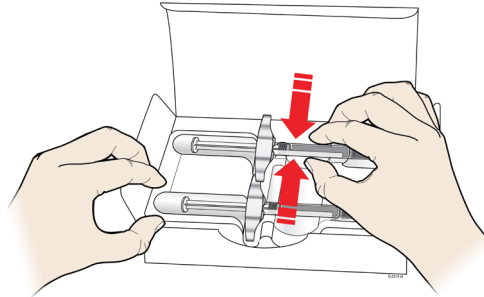
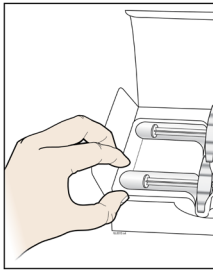
Using your AMJEVITA prefilled syringe

- It is important that you do not try to give the injection unless you or your caregiver has received training from your doctor or nurse.
- **Do not** use the AMJEVITA prefilled syringe after the expiration date on the label.
- **Do not** shake the AMJEVITA prefilled syringe.
- **Do not** remove the needle cap from the AMJEVITA prefilled syringe until you are ready to inject.
- **Do not** use the AMJEVITA prefilled syringe if it has been frozen.
- **Do not** use the AMJEVITA prefilled syringe if it has been dropped on a hard surface. Part of the AMJEVITA prefilled syringe may be broken even if you cannot see the break. Use a new AMJEVITA prefilled syringe, and call 1-800-77-AMGEN (1-800-772-6436).
- The AMJEVITA prefilled syringe is not made with natural rubber latex.
- For more information or help call 1-800-77-AMGEN (1-800-772-6436).

Step 1: Prepare

A Remove the prefilled syringe carton from the refrigerator.

Remove the number of AMJEVITA prefilled syringes you need for your injection from the carton. Grab the **syringe barrel** to remove the prefilled syringe from the tray as shown.



Grab Syringe Barrel

Place your finger or thumb on the edge of the tray to secure it while you remove the syringe.

Put the original carton with any unused prefilled syringes back in the refrigerator.

For safety reasons:

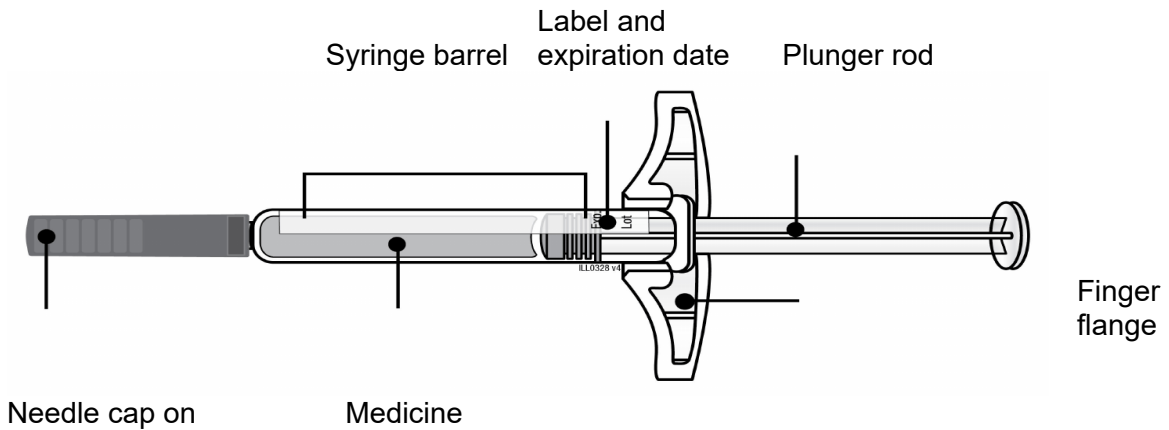
- **Do not** grab the plunger rod.
- **Do not** grab the needle cap.
- **Do not** remove the needle cap until you are ready to inject.
- **Do not** remove the finger flange. The finger flange is part of the syringe.

For a more comfortable injection, leave the syringe at room temperature for **15 to 30** minutes before injecting.

- **Do not** put the syringe back in the refrigerator once it has reached room temperature.
- **Do not** try to warm the syringe by using a heat source such as hot water or microwave.
- **Do not** leave the syringe in direct sunlight.
- **Do not** shake the syringe.

Important: Always hold the prefilled syringe by the syringe barrel.

B Inspect the AMJEVITA prefilled syringe.



Always hold the syringe by the syringe barrel.

Make sure the medicine in the syringe is clear and colorless to slightly yellow.

- **Do not** use the syringe if:
 - The medicine is cloudy or discolored, or contains flakes or particles.
 - Any part appears cracked or broken.
 - The needle cap is missing or not securely attached.
 - The expiration date printed on the label has passed.

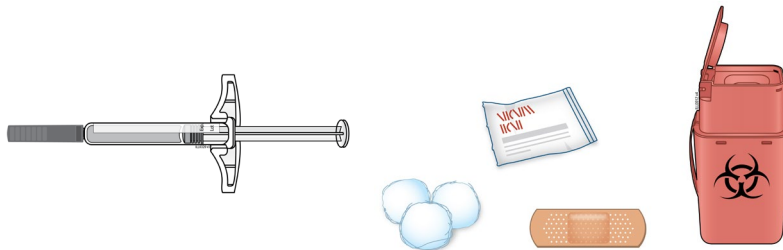
In all cases, use a new syringe, and call 1-800-77-AMGEN (1-800-772-6436).

C Gather all materials needed for your injection(s).

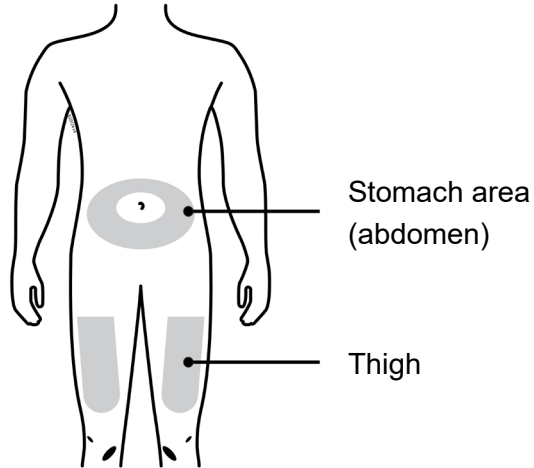
Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the:

- New syringe(s)
- Alcohol wipes
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



D Prepare and clean your injection site(s).



You can use:

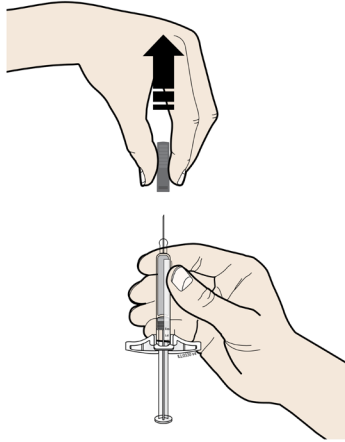
- Your thigh
- Stomach area (abdomen), except for a 2-inch area right around your navel (belly button)

Clean your injection site with an alcohol wipe. Let your skin dry.

- **Do not** fan or blow on the clean area.
- **Do not** touch this area again before injecting.
- Choose a different site each time you give yourself an injection. If you need to use the same injection site, make sure it is not the same spot on the injection site you used the last time.
 - **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.
- If you have psoriasis, you should avoid injecting directly into raised, thick, red, or scaly skin patch or lesion.
- **Do not** inject through your clothes.

Step 2: Get ready

E Hold the prefilled syringe by the syringe barrel with the needle cap pointing up. Carefully pull the needle cap straight off and away from your body when you are ready to inject.

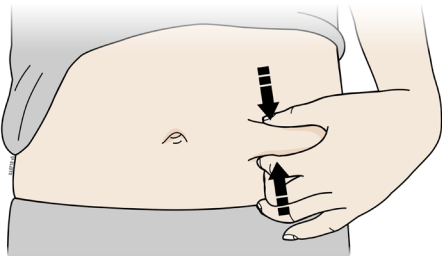


It is normal to see a drop of liquid at the end of the needle.

- **Do not** twist or bend the needle cap.
- **Do not** put the needle cap back onto the syringe.
- **Do not** remove the needle cap from the syringe until you are ready to inject.

Important: Throw the needle cap into the sharps disposal container provided.

F Pinch your injection site to create a firm surface.

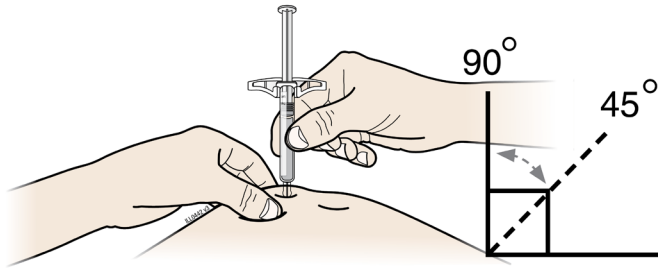


Pinch the skin firmly between your thumb and fingers, creating an area about **2** inches wide.

Important: Keep the skin pinched while injecting.

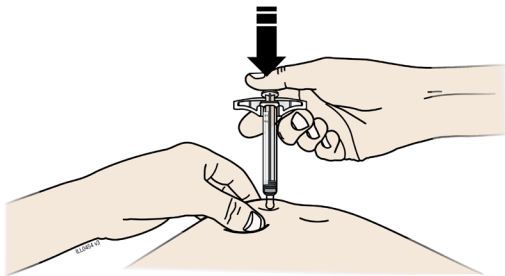
Step 3: Inject

G Hold the pinch. With the needle cap off, insert the syringe into your skin at 45 to 90 degrees.

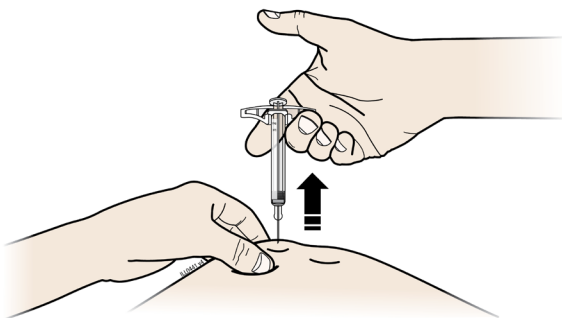


Do not place your finger on the plunger rod while inserting the needle.

H Using slow and constant pressure, push the plunger rod all the way down until it reaches the bottom. **Do not** pull back the plunger rod while the needle is inserted.



I When done, release your thumb, and gently pull the syringe off of your skin.



Step 4: Finish

J Discard (throw away) the used prefilled syringe and the needle cap. **Do not** use any medicine that is left in the used syringe.



- Put the used AMJEVITA prefilled syringe in an FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the prefilled syringe 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 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>
- **Do not** reuse the syringe.
- **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.

Important: Always keep the sharps disposal container out of the reach of children.

K Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site.

Do not rub the injection site. Apply an adhesive bandage if needed.

Please see the Medication Guide for AMJEVITA and accompanying Prescribing Information.

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



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US License Number 1080

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