

## **Instructions for Use**

### **Welcome!**

The AMJEVITA™ SureClick® autoinjector is a single-use prefilled autoinjector. Consult your doctor if you have any questions about your dose.

**Your doctor has prescribed AMJEVITA SureClick autoinjector 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.**

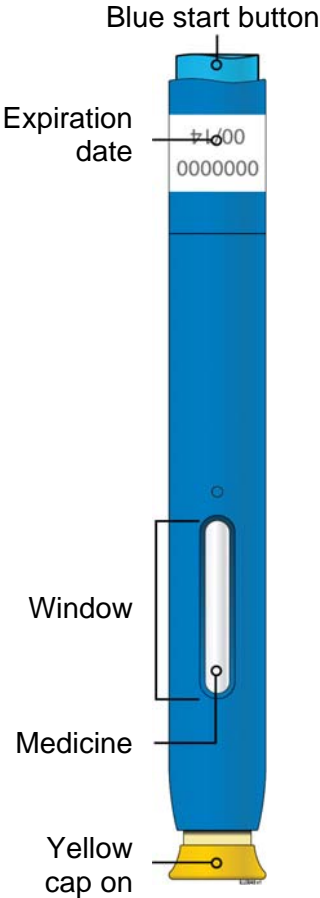
**Please read all of the instructions before using AMJEVITA SureClick autoinjector.** Call your doctor if you or your caregiver have any questions about the right way to inject AMJEVITA.

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

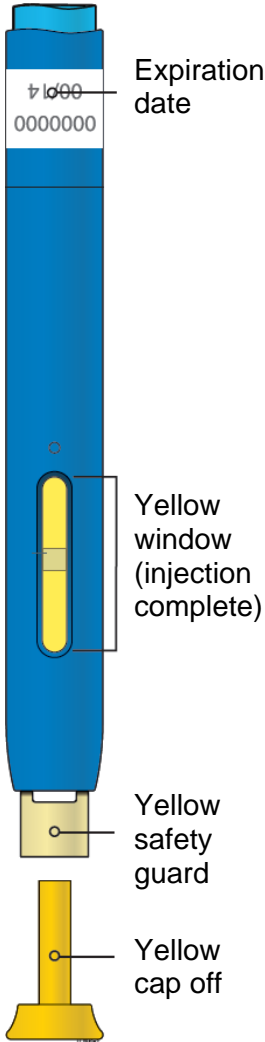
Single-Use Prefilled SureClick® Autoinjector

**Guide to parts**

**Before use**



**After use**



**Important:** Needle is inside

## Important

**Before you use an AMJEVITA SureClick autoinjector, read this important information:**

### **Storing your AMJEVITA SureClick autoinjectors**

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

### **Using your AMJEVITA SureClick autoinjector**

- 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 SureClick autoinjector after the expiration date on the label.
- **Do not** shake the AMJEVITA SureClick autoinjector.
- **Do not** remove the yellow cap from the AMJEVITA SureClick autoinjector until you are ready to inject.
- **Do not** use the AMJEVITA SureClick autoinjector if it has been frozen.
- **Do not** use the AMJEVITA SureClick autoinjector if it has been dropped on a hard surface. Part of the AMJEVITA SureClick autoinjector may be broken even if you cannot see the break. Use a new AMJEVITA SureClick autoinjector, and call 1-800-77-AMGEN (1-800-772-6436).
- This product contains dry natural rubber, which is made from latex, within the yellow cap. Tell your doctor if you are allergic to latex.

For more information or help or call 1-800-77-AMGEN (1-800-772-6436).

## Step 1: Prepare

**A** Remove 1 AMJEVITA SureClick autoinjector from the package.

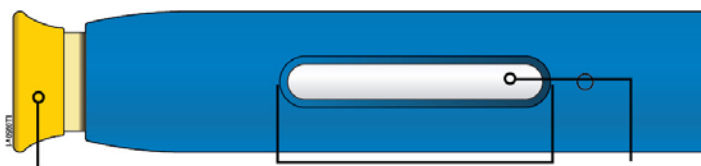
Carefully lift the autoinjector straight up out of the box.

Put the original package with any unused autoinjectors back in the refrigerator.

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

- **Do not** put the autoinjector back in the refrigerator once it has reached room temperature.
- **Do not** try to warm the autoinjector by using a heat source such as hot water or microwave.
- **Do not** shake the autoinjector.
- **Do not** remove the yellow cap from the autoinjector yet.

**B** Inspect the AMJEVITA SureClick autoinjector.



Yellow cap on

Window

Medicine

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

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

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

**C** Gather all materials needed for your injection.

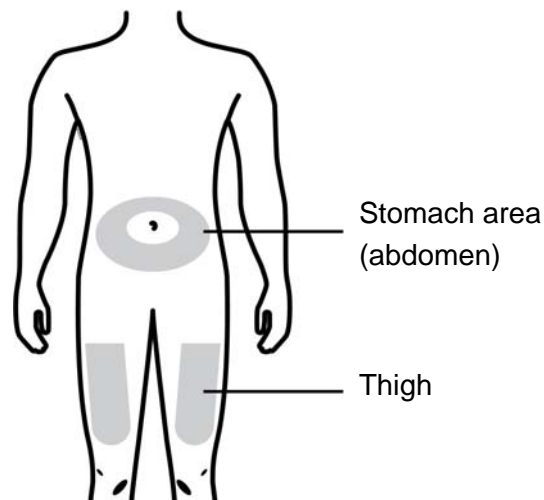
Wash your hands thoroughly with soap and water.

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

- New autoinjector
- Alcohol wipes
- Cotton ball or gauze pad
- Adhesive bandage
- Sharps disposal container



**D** Prepare and clean your injection site.



**You can use:**

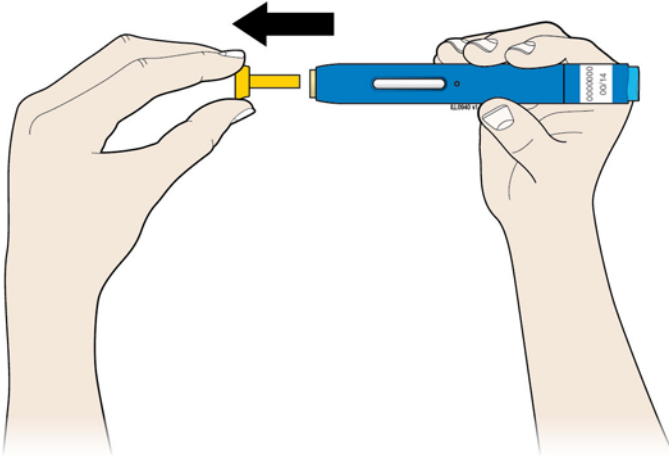
- Your thigh
- Stomach area (abdomen), except for a 2-inch area right around your navel (belly button)

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 Pull yellow cap straight off when you are ready to inject.

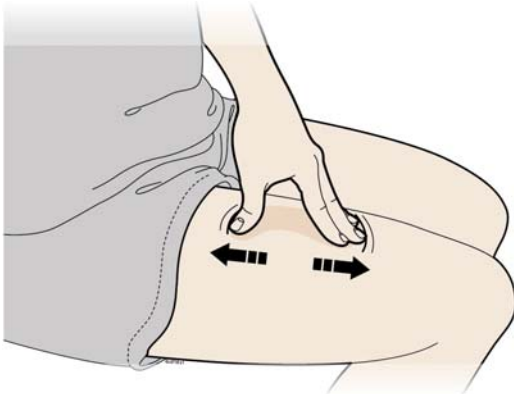


It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

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

F Stretch or pinch your injection site to create a firm surface.

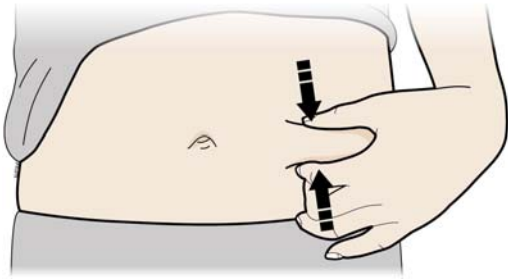
### Stretch method



Stretch the skin firmly by moving your thumb and fingers in opposite directions, creating an area about **2** inches wide.

OR

## Pinch method

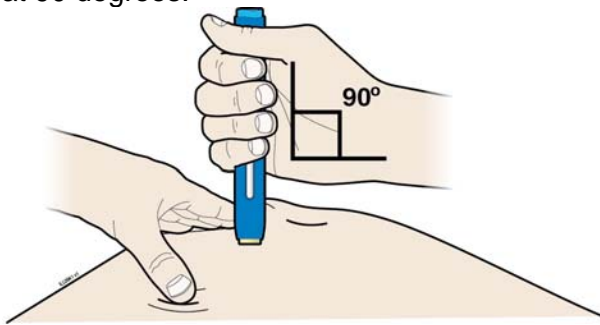


Pinch the skin firmly between your thumb and fingers, creating an area about **2** inches wide.

**Important:** Keep the skin stretched or pinched while injecting.

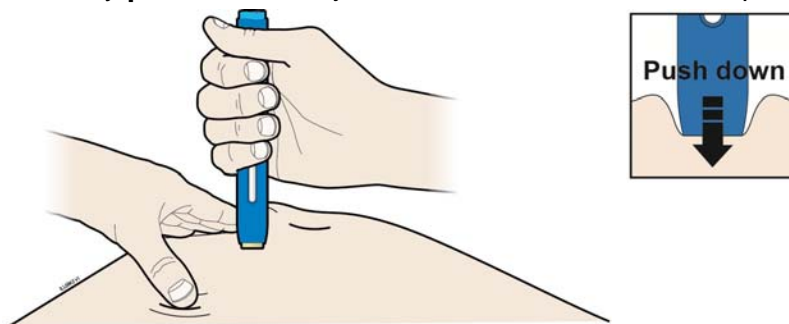
## Step 3: Inject

**G** Hold the stretch or pinch. With the yellow cap off, **place** the autoinjector on your skin at 90 degrees.



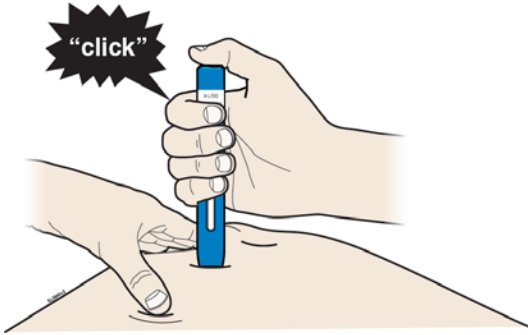
**Important:** Do not touch the blue start button yet.

**H** Firmly **push** the autoinjector down onto skin until it stops moving.

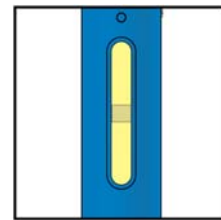
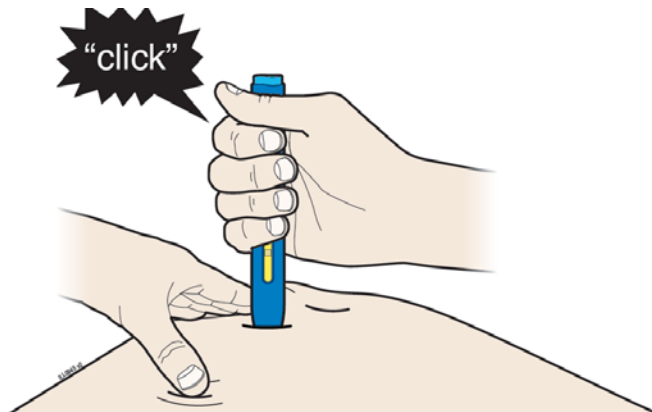


**Important:** You must push all the way down but do not touch blue start button until you are ready to inject.

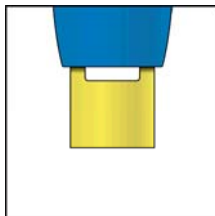
I When you are ready to inject, **press** the blue start button.



J Keep **pushing** down on your skin. Your injection could take about **10** seconds.



Window turns yellow  
when injection is done



**Note:** After you remove autoinjector from your skin, the needle will be automatically covered.

**Important:** When you remove the autoinjector, if the window has not turned yellow, or if it looks like the medicine is still injecting, this means you have not received a full dose. Call your doctor immediately.



#### Step 4: Finish

**K** Discard (throw away) the used autoinjector and the yellow cap.



- Put the used SureClick autoinjector in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) the SureClick autoinjector 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 autoinjector.
- **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.

**L** 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.

## Commonly asked questions

### **What will happen if I press the blue start button before I am ready to do the injection on my skin?**

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Even when you press the blue start button, the injection will only happen when the yellow safety guard is also pushed into the autoinjector.

### **Can I move the autoinjector around on my skin while I am choosing an injection site?**

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It is okay to move the autoinjector around on the injection site as long as you **do not** press the blue start button. However, if you press the blue start button and the yellow safety guard is pushed into the autoinjector, the injection will begin.

### **Can I release the blue start button after I start my injection?**

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You can release the blue start button, but continue to hold the autoinjector firmly against your skin during the injection.

### **Will the blue start button pop up after I release my thumb?**

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The blue start button may not pop up after you release your thumb if you held your thumb down during the injection. This is okay.

### **What do I do if I didn't hear a click after pushing the device down on my skin for 10 seconds?**

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If you didn't hear a click, you can confirm a complete injection by checking that the window has turned yellow.

### **Whom do I contact if I need help with the autoinjector or my injection?**

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If you have any questions about the autoinjector, its storage, or about your injection, call 1-800-77-AMGEN (1-800-772-6436) for help.

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



#### **Manufactured by:**

Amgen Inc.  
One Amgen Center Drive  
Thousand Oaks, California 91320-1799  
US License Number 1080

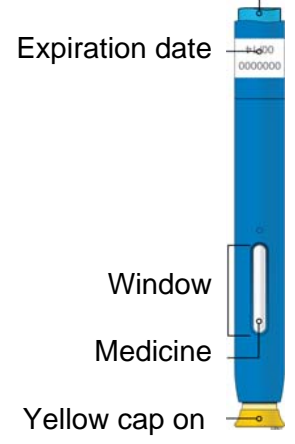
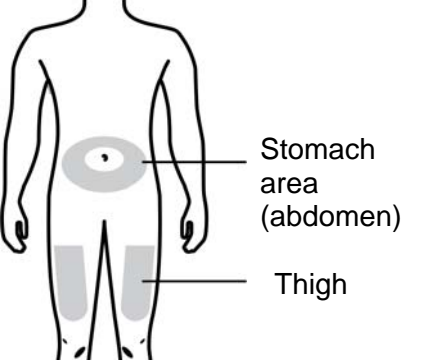
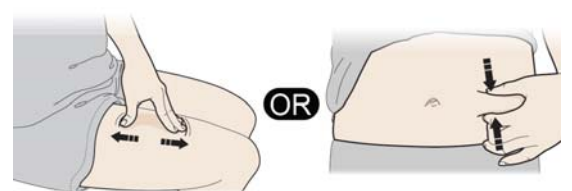
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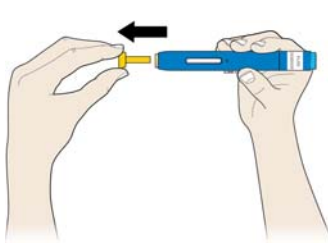
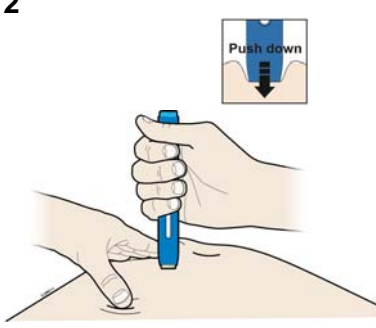

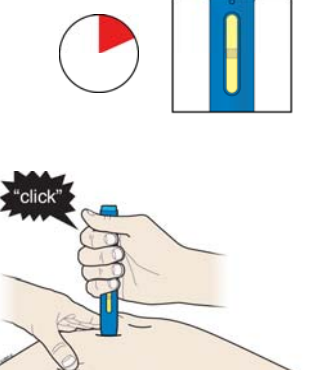
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Issued: 9/2016

v1

**APPENDIX 1 – REFERENCE GUIDE**

<p><b>Side 1</b></p>	<p><b>Reference Guide</b>                  AMJEVITA™ (am-jeh-vee'-tah) (adalimumab-atto) injection, for subcutaneous use                  Single-Use Prefilled SureClick® Autoinjector</p>	<p>Read all instructions in carton before use.</p>	<p>(barcode)                  &lt;part number&gt;</p>
<p>Guide to parts</p>	<p>Prepare and clean your injection site.</p>	<p>Stretch or pinch your injection site to create a firm surface.</p>	
<p>Blue start button</p> <p>Expiration date</p>  <p>Window</p> <p>Medicine</p> <p>Yellow cap on</p>	 <p>Stomach area (abdomen)</p> <p>Thigh</p>	 <p><b>TURN OVER TO CONTINUE.....</b></p>	

<p><b>Side 2</b> Reference Guide</p>		<p><b>Manufactured by:</b>                  Amgen Inc.                  © 2016 All rights reserved.                  1xxxxxx                  Issued: 9/2016 v1</p>	<p><b>READ OTHER SIDE FIRST</b></p>
<p>Pull yellow cap straight off.</p>	<p>Firmly <b>push</b> autoinjector down onto skin.</p>	<p><b>Press</b> blue start button.</p>	<p>Keep <b>pushing</b> down on skin for about 10 seconds.</p>
<p><b>1</b></p> 	<p><b>2</b></p> 	<p><b>3</b></p> 	<p><b>4</b></p> 

## **Instructions for Use**

### **Welcome!**

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

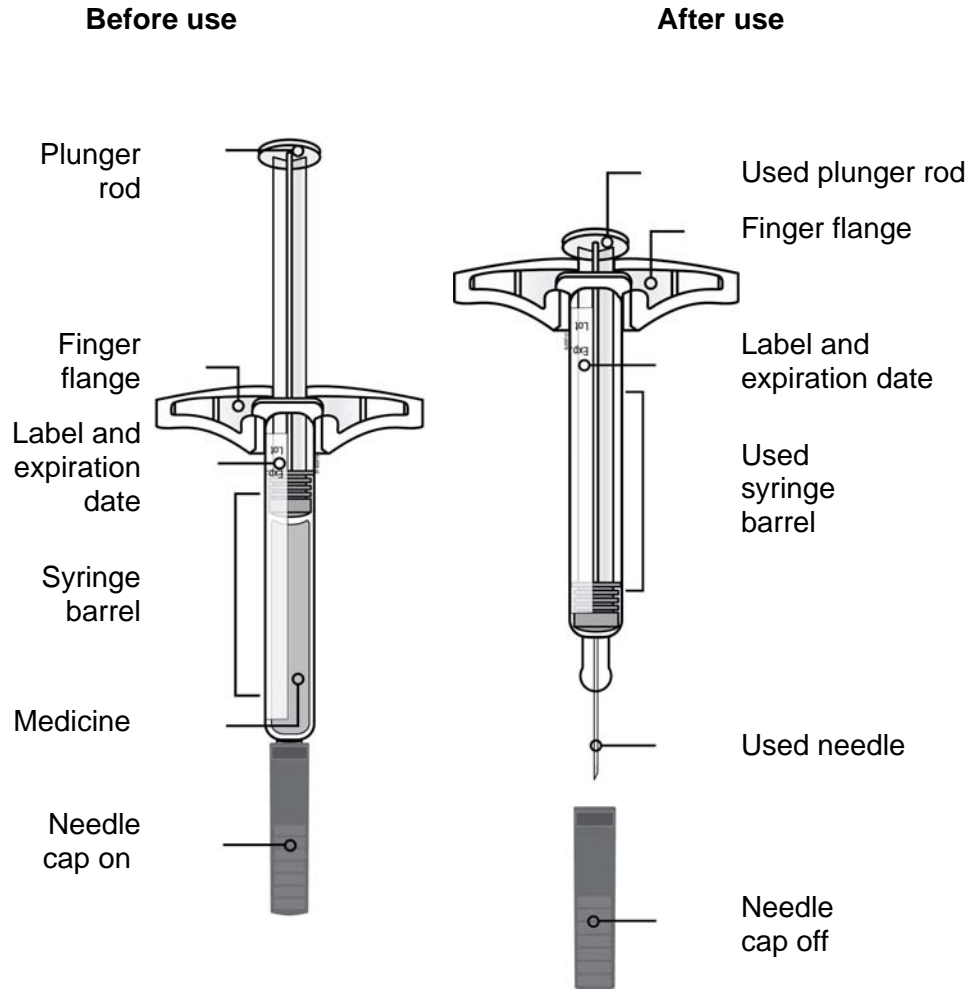
**Your doctor has prescribed AMJEVITA prefilled syringe for your injections. If your doctor decides that you or a caregiver may be able to give your injections of AMJEVITA at home, you should receive training on the right way to prepare and inject AMJEVITA. Do not try to inject yourself until you have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

**Guide to parts**



**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 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

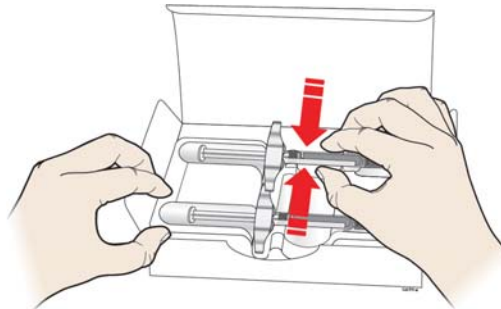
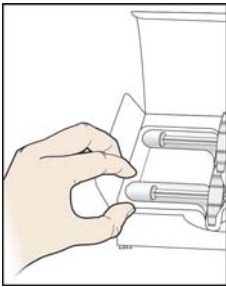
- It is important that you do not try to give the injection unless you or your caregiver has received training from your doctor or nurse.
- **Do not** use the AMJEVITA prefilled syringe after the expiration date on the label.
- **Do not** shake the AMJEVITA prefilled syringe.
- **Do not** remove the 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).
- This product contains dry natural rubber, which is made from latex, within the needle cap. Tell your doctor if you are allergic to 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:

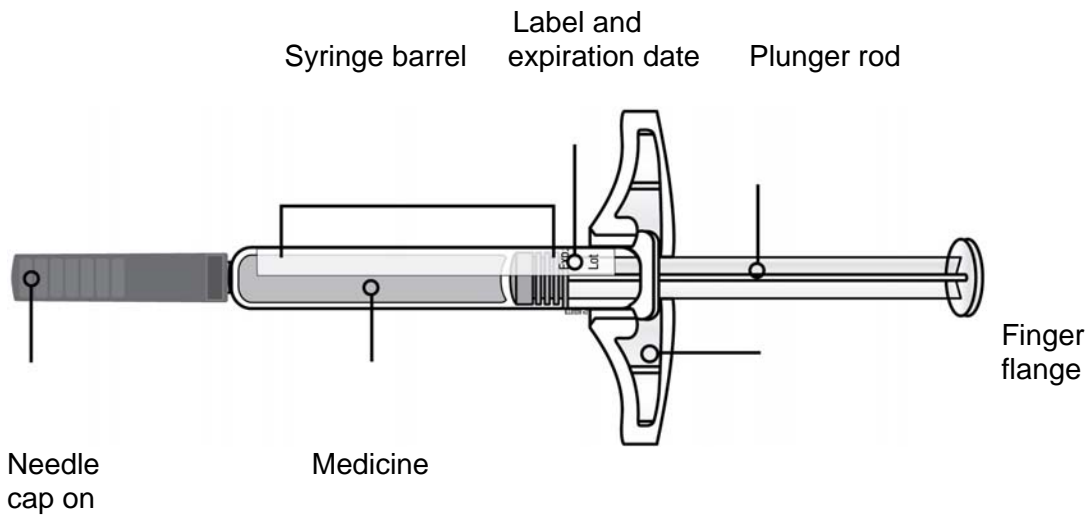
- **Do not** grab the plunger rod.
- **Do not** grab the needle cap.
- **Do not** remove the needle cap until you are ready to inject.
- **Do not** remove the finger flange. The finger flange is part of the syringe.

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.

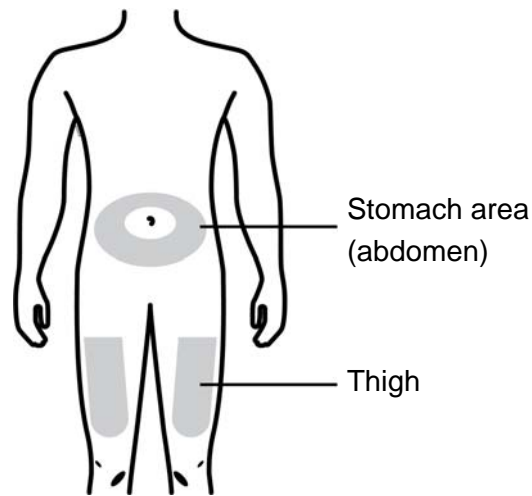
On a clean, well-lit work surface, place the:

- 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:**

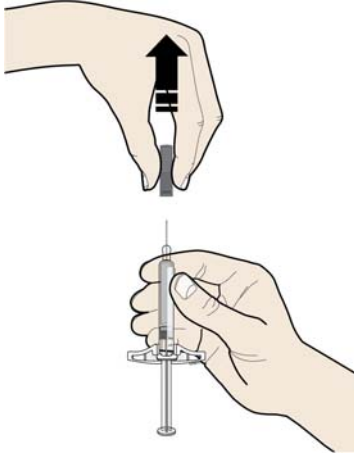
- Your thigh
- Stomach area (abdomen), except for a **2-inch** area right around your navel (belly button)

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.

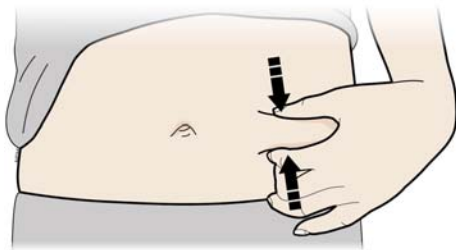


**It is normal to see a drop of liquid at the end of the needle.**

- **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.

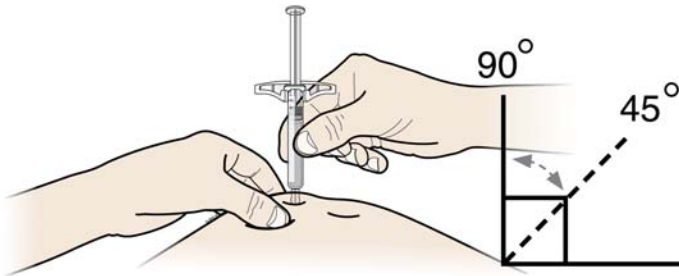


Pinch the skin firmly between your thumb and fingers, creating an area about **2** inches wide.

**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.

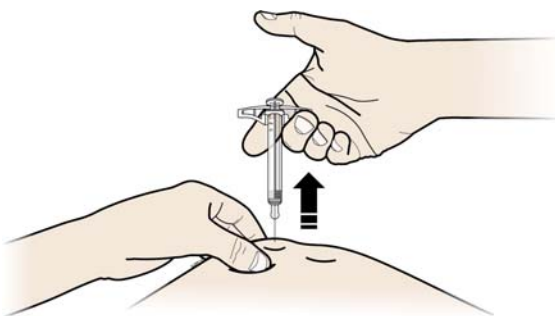


**Do not** place your finger on the plunger rod while inserting the needle.

**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.



**Manufactured by:**

Amgen Inc.

One Amgen Center Drive

Thousand Oaks, California 91320-1799

US License Number 1080

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Issued: 9/2016

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