Instructions for Use

Welcome!

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

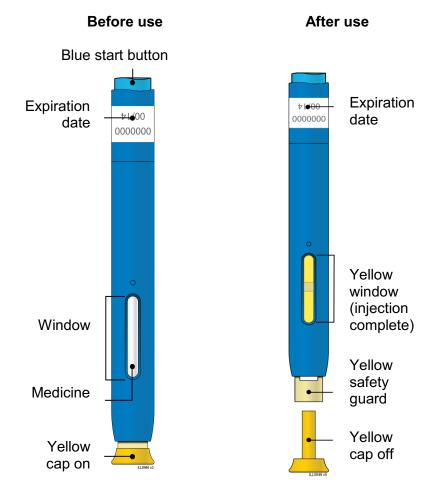
Your doctor has prescribed AMJEVITA SureClick autoinjector for your injections. If your doctor decides that you or a caregiver may be able to give your injections of AMJEVITA at home, you should receive training on the right way to prepare and inject AMJEVITA. Do not try to inject yourself until you 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-Dose Prefilled SureClick® Autoinjector

Guide to parts



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 at 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).
- The AMJEVITA SureClick autoinjector is not made with natural rubber 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.

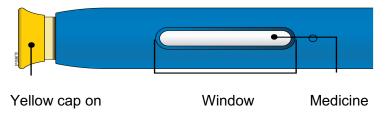
Carefully lift the autoinjector straight up out of the box.

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.



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.

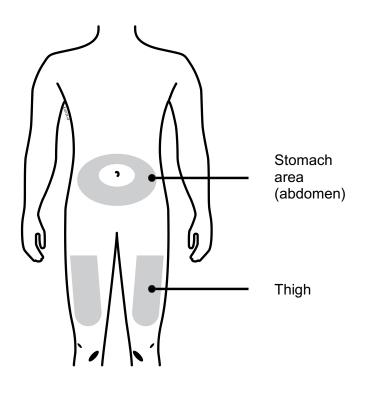
Wash your hands thoroughly with soap and water.

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)

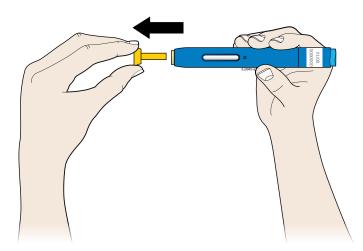
Clean your injection site with an alcohol wipe. Let your skin dry.

- **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, only when you are ready to inject.

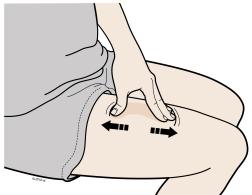


It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

- **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.

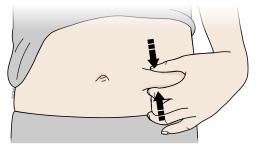
Stretch method



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



Pinch method

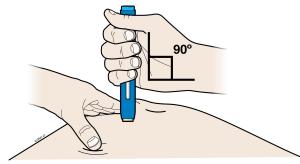


Pinch the skin firmly between your thumb and fingers, creating an area about **2** inches wide.

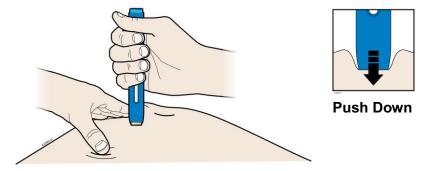
Important: Keep the skin stretched or pinched while injecting.

Step 3: Inject

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



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

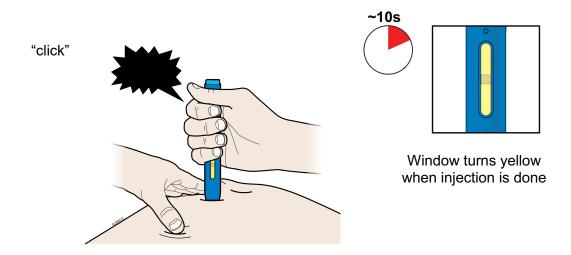


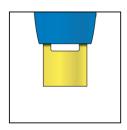
Important: You must push all the way down but do not touch blue start button until you are ready to inject.

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.



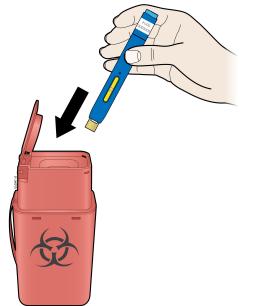


Note: After you remove autoinjector from your skin, the needle will be automatically covered.

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:
 - o made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - o upright and stable during use,
 - o leak-resistant, and
 - o 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?

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?

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?

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?

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?

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?

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.

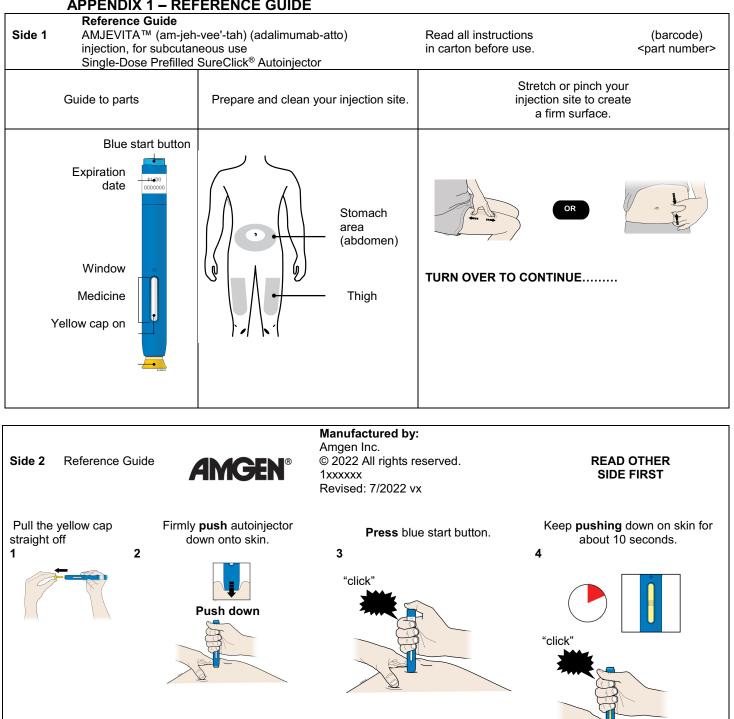
This Instructions for Use has been approved by the U.S. Food and Drug Administration.

AMGEN

Manufactured by:

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

© 2022 Amgen Inc. All rights reserved. 1xxxxx Revised: 07/2022 V2



APPENDIX 1 – REFERENCE GUIDE

Instructions for Use

Welcome!

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

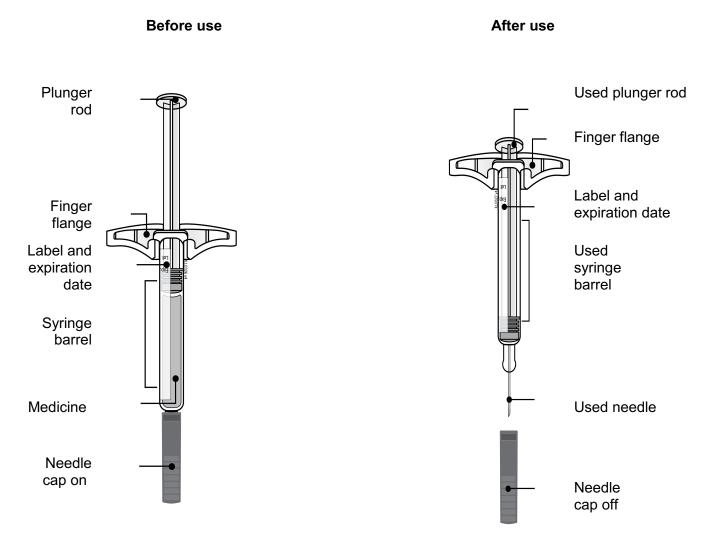
Your doctor has prescribed AMJEVITA prefilled syringe for your injections. If your doctor decides that you or a caregiver may be able to give your injections of AMJEVITA at home, you should receive training on the right way to prepare and inject AMJEVITA. Do not try to inject yourself until you have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



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.

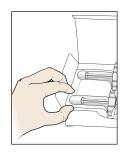
Using your AMJEVITA prefilled syringe

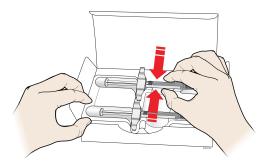
- It is important that you do not try to give the injection unless you or your caregiver has received training from your doctor or nurse.
- **Do not** use the AMJEVITA prefilled syringe after the expiration date on the label.
- **Do not** shake the AMJEVITA prefilled syringe.
- **Do not** remove the 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:

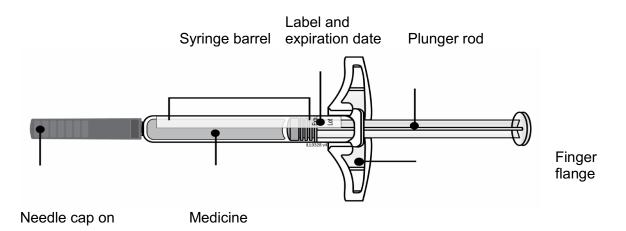
- **Do not** grab the plunger rod.
- **Do not** grab the needle cap.
- Do not remove the needle cap until you are ready to inject.
- **Do not** remove the finger flange. The finger flange is part of the syringe.

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.
 - \circ $\;$ The needle cap is missing or not securely attached.
 - The expiration date printed on the label has passed.

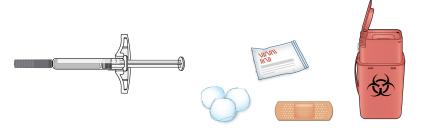
In all cases, use a new syringe, and call 1-800-77-AMGEN (1-800-772-6436).

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

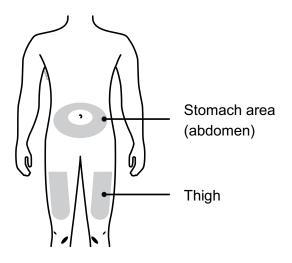
Wash your hands thoroughly with soap and water.

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:

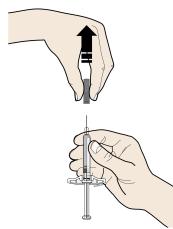
- Your thigh
- Stomach area (abdomen), except for a 2-inch area right around your navel (belly button)

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.

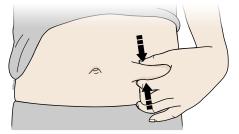


It is normal to see a drop of liquid at the end of the needle.

- **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.

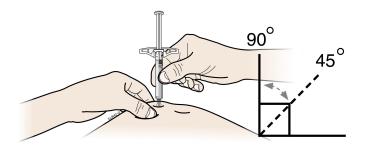


Pinch the skin firmly between your thumb and fingers, creating an area about **2** inches wide.

Important: Keep the skin pinched while injecting.

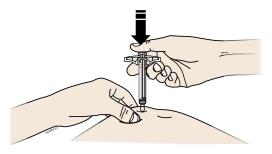
Step 3: Inject

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

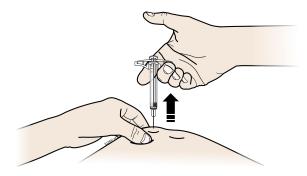


Do not place your finger on the plunger rod while inserting the needle.

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:
 - o made of a heavy-duty plastic,
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
 - o upright and stable during use,
 - o leak-resistant, and
 - o 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

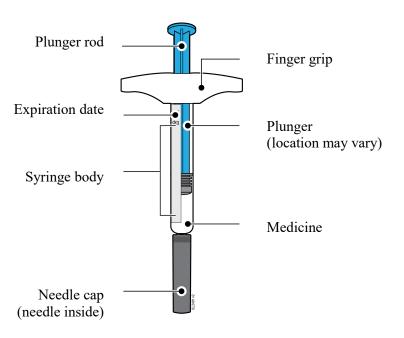
© 2022 Amgen Inc. All rights reserved. 1xxxxx Revised: 7/2022 V2

INSTRUCTIONS FOR USE AMJEVITA[™] (am-jeh-vee'-tah) (adalimumab-atto) 10 mg/0.2 mL injection, for subcutaneous use single-dose prefilled syringe

This Instructions for Use contains information on how to inject AMJEVITA with a prefilled syringe.

If your healthcare provider decides that a caregiver may be able to give your injections of AMJEVITA at home, they should receive training on the right way to prepare and inject AMJEVITA. Do not try to inject until they have been shown the right way to give the injections by your healthcare provider or nurse.

The medicine in the AMJEVITA prefilled syringe is for injection under the skin (subcutaneous injection). See the AMJEVITA Medication Guide for information about AMJEVITA.



Getting to know your prefilled syringe

1. Important Information You Need to Know Before Injecting AMJEVITA

- It is important that you do not try to give the injection until you have fully read and understood this Instructions for Use.
- **Do not** use the syringe if the carton is damaged or the seal is broken.
- **Do not** use the syringe after the expiration date on the label.
- **Do not** shake the syringe.
- **Do not** remove the needle cap from the syringe until you are ready to inject.
- **Do not** use the syringe if it has been frozen.
- **Do not** use the syringe if it has been dropped on a hard surface. Part of the syringe may be broken even if you cannot see the break. Use a new syringe, and call 1-800-77-AMGEN (1-800-772-6436).
- The syringe is not made with natural rubber latex.

Important: Keep the syringe and sharps disposal container out of the sight and reach of children.

Frequently asked questions:

For additional information and answers to frequently asked questions, visit www.amjevita.com.

Where to get help:

If you want more information or help using AMJEVITA:

- Contact your healthcare provider,
- Visit www.amjevita.com, or
- Call 1-800-77-AMGEN (1-800-772-6436)

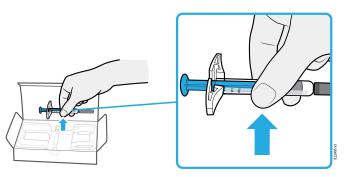
2. Storing and Preparing to Inject AMJEVITA



2a Refrigerate the syringe carton until you are ready to use it.

- Keep the syringe in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the syringe in the original carton to protect it from light or physical damage.
- **Do not** freeze the syringe.
- **Do not** store the syringe in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.

Important: Keep the syringe out of the sight and reach of children.



2b Grasp the syringe by the body and remove it from the carton.

- **Do not** grab the finger grip, plunger rod, or the needle cap.
- Remove the number of syringes you need for your injection.
- Put any unused syringes back into the refrigerator.





2c Wait 15 to 30 minutes for the syringe to reach room temperature.

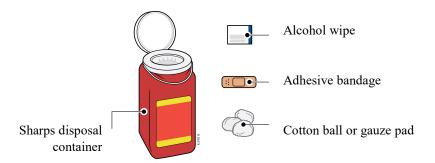
- Let the syringe warm up naturally.
- **Do not** heat the syringe with hot water, a microwave or direct sunlight.
- **Do not** shake the syringe at any time.
- Using the syringe at room temperature allows for a more comfortable injection.



2d You may keep AMJEVITA at room temperature for up to 14 days, if needed.

- For example when you are traveling, you may keep AMJEVITA at room temperature.
 - \circ Keep it at room temperature between 68° F to 77° F (20° C to 25° C).
 - **Do not** put it back in the refrigerator.
 - Record the date you removed it from the refrigerator and use it within 14 days.

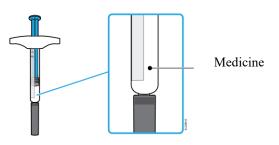
Important: Place the syringe in a sharps disposal container if it has reached room temperature and has not been used within **14** days.



2e Gather and place the following items for your injection on a clean, flat, and well-lit surface:

- AMJEVITA syringe (room temperature)
- Sharps disposal container [see Disposing of AMJEVITA and Checking the Injection Site]
- Alcohol wipe
- Adhesive bandage
- Cotton ball or gauze pad

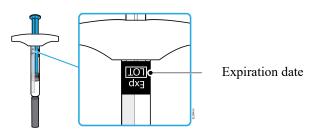
3. Getting Ready for Your Injection



3a Inspect the medicine. It should be clear and colorless to pale yellow.

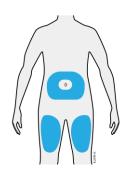
- It is okay to see air bubbles in the syringe.
- Do not use AMJEVITA if the medicine is cloudy, discolored or has flakes.

Important: If the medicine is cloudy, discolored or has flakes or if the syringe is damaged or expired, call 1-800-77-AMGEN (1-800-722-6436).



3b Check the expiration date (Exp.) and inspect the syringe for damage.

- **Do not** use the syringe if the expiration date has passed.
- **Do not** use the syringe if:
 - \circ the needle cap is missing or loose.
 - \circ it has cracks or broken parts.
 - it has been dropped on a hard surface.
- Make sure you have the right medicine and dose.



3c Inject into 1 of these locations.

- Inject into the front of your thigh or stomach (except for 2 inches around your belly button).
- Choose a different site for each injection.

Important: Avoid areas with scars, stretch marks or where the skin is tender, bruised, red or hard.



3d Wash hands thoroughly with soap and water.

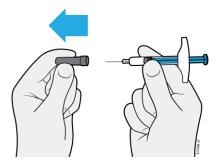


3e Clean the injection site with an alcohol wipe.

- Let the skin dry on its own.
- **Do not** touch this area again before injecting.

4. Injecting AMJEVITA

Important: Only remove the needle cap when you can inject right away (within 5 minutes) because the medicine can dry out.



4a Pull the needle cap straight off while holding the syringe body.

- **Do not** twist or bend the needle cap.
- Never put the needle cap back on. It may damage the needle.
- **Do not** let anything touch the needle after you remove the needle cap.
- **Do not** place the uncapped syringe on any surface after you remove the needle cap.
- **Do not** try to push air bubbles out of the syringe. It is okay to see air bubbles.
- It is normal to see a drop of medicine come out of the needle.

Important: Never put the needle cap back on to avoid accidental needlestick injury.



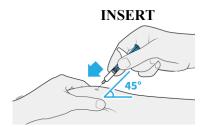
4b Place the needle cap in the sharps disposal container.



4c Pinch the skin around the injection site before injection.

- Pinch the skin between the thumb and pointer (index) finger to create a bump for injection.
- If possible, the bump should be about 2 inches wide.

Important: Continue to pinch the skin until the injection is complete.



4d Insert the needle into the pinched skin at about a 45-degree angle.

• **Do not** place your finger on the plunger rod while inserting the needle, as this may result in lost medicine.

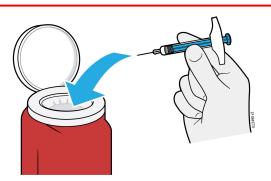


4e Slowly press the plunger rod all the way down until it reaches the bottom to inject the medicine.

- **Do not** pull back on the plunger rod at any time.
- **Do not** remove the syringe until all of the medicine has been injected.

5. Disposing of AMJEVITA and Checking the Injection Site

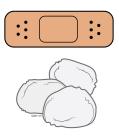
Important: Never put the needle cap back on.



5a Place the used syringe in an FDA-cleared sharps disposal container right away after use.

Important: Do not throw away the syringe in your household trash.

• **Do not** reuse the syringe.



5b Check the injection site.

- **Do not** rub the injection site.
- If there is blood, press a cotton ball or gauze pad on the injection site. Apply an adhesive bandage if necessary.

Additional information about your sharps disposal container

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.

Disposing of sharps containers:

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 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.

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

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

AMJEVITA (adalimumab-atto)



Manufactured by: Amgen Inc. One Amgen Center Drive Thousand Oaks, California 91320-1799 US License Number 1080 ©2023 Amgen Inc. All rights reserved. nnnnnnnn Issued: 04/2023

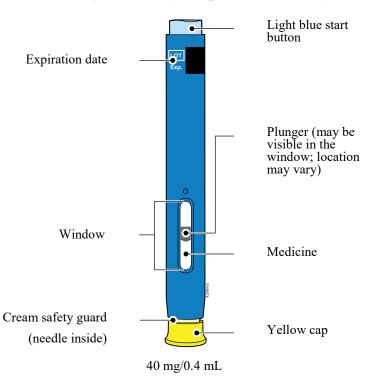
INSTRUCTIONS FOR USE AMJEVITA[™] (am-jeh-vee'-tah) (adalimumab-atto) injection, for subcutaneous use 40 mg/0.4 mL single-dose prefilled SureClick[®] autoinjector

This Instructions for Use contains information on how to inject AMJEVITA with a SureClick autoinjector.

If your healthcare provider 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 healthcare provider or nurse.

The medicine in the AMJEVITA autoinjector is for injection under the skin (subcutaneous injection). See the AMJEVITA Medication Guide for information about AMJEVITA.

Getting to know your prefilled autoinjector



1. Important Information You Need to Know Before Injecting AMJEVITA

- It is important that you do not try to give the injection until you have fully read and understood this Instructions for Use.
- **Do not** use the autoinjector if the carton is damaged or the seal is broken.
- **Do not** use the autoinjector after the expiration date on the label.
- **Do not** shake the autoinjector.
- Do not remove the yellow cap from the autoinjector until you are ready to inject.
- **Do not** use the autoinjector if it has been frozen.
- **Do not** use the autoinjector if it has been dropped on a hard surface. Part of the autoinjector may be broken even if you cannot see the break. Use a new autoinjector, and call 1-800-77-AMGEN (1-800-772-6436).
- The autoinjector is not made with natural rubber latex.

Important: Keep the autoinjector and sharps disposal container out of the sight and reach of children.

Frequently asked questions:

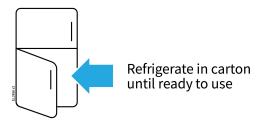
For additional information and answers to frequently asked questions, visit www.amjevita.com.

Where to get help:

If you want more information or help using AMJEVITA:

- Contact your healthcare provider,
- Visit **www.amjevita.com**, or
- Call 1-800-77-AMGEN (1-800-772-6436)

2. Storing and Preparing to Inject AMJEVITA



2a Refrigerate the autoinjector carton until you are ready to use it.

- Keep the autoinjector in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the autoinjector in the original carton to protect it from light or physical damage.
- **Do not** freeze the autoinjector.
- **Do not** store the autoinjector in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.

Important: Keep the autoinjector out of the sight and reach of children.



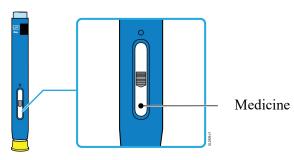
2b Wait 15 to 30 minutes for the autoinjector to reach room temperature.

- Remove the number of autoinjectors you need for your injection and put any unused autoinjectors back into the refrigerator.
- Let the autoinjector warm up naturally.
- Do not heat the autoinjector with hot water, a microwave, or direct sunlight.
- **Do not** shake the autoinjector at any time.
- Using the autoinjector at room temperature makes sure the full dose is delivered and allows for a more comfortable injection.



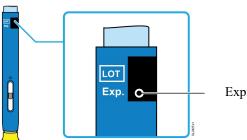
- 2c You may keep AMJEVITA at room temperature for up to 14 days, if needed.
 - For example, when you are traveling, you may keep AMJEVITA at room temperature.
 - \circ Keep it at room temperature between 68°F to 77°F (20°C to 25°C).
 - **Do not** put it back in the refrigerator.
 - Record the date you removed it from the refrigerator and use it within 14 days.

Important: Place the autoinjector in a sharps disposal container if it has reached room temperature and has not been used within 14 days.



- 2d Inspect the medicine. It should be clear and colorless to pale yellow.
 - It is okay to see air bubbles in the autoinjector.
 - **Do not** use AMJEVITA if the medicine is cloudy, discolored, or has flakes or particles.

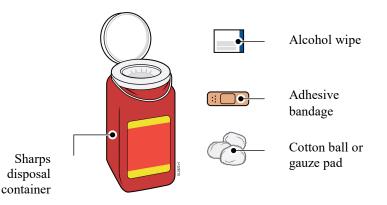
Important: If the medicine is cloudy, discolored, or has flakes or particles, or if the autoinjector is damaged or expired, call 1-800-77-AMGEN (1-800-772-6436).



Expiration date

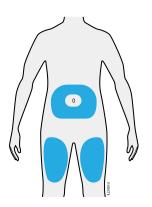
- 2e Check the expiration date (Exp.) and inspect the autoinjector for damage.
 - **Do not** use the autoinjector if the expiration date has passed.
 - **Do not** use the autoinjector if:
 - the yellow cap is missing or loose.
 - it has cracks or broken parts.
 - it has been dropped on a hard surface.
 - Make sure you have the right medicine and dose.

3. Getting Ready for Your Injection



3a Gather and place the following items for your injection on a clean, flat, and well-lit surface:

- AMJEVITA autoinjector (room temperature)
- Sharps disposal container [see Disposing of AMJEVITA and Checking the Injection Site]
- Alcohol wipe
- Adhesive bandage
- Cotton ball or gauze pad



3b Inject into 1 of these locations.

- Inject into the front of your thigh or stomach (except for 2 inches around your belly button).
- Choose a different site for each injection.

Important: Avoid areas with scars or stretch marks, or where the skin is tender, bruised, red, or hard.



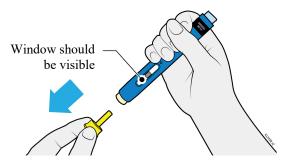


3d Clean the injection site with an alcohol wipe.

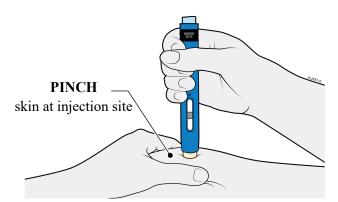
- Let the skin dry on its own.
- **Do not** touch this area again before injecting.

4. Injecting AMJEVITA

Important: Only remove the yellow cap when you can inject right away (within 5 minutes) because the medicine can dry out. **Do not** recap.



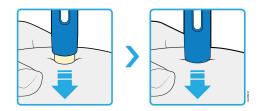
- 4a Grasp the autoinjector so you can see the window. Pull the yellow cap straight off. You may need to pull hard.
 - **Do not** twist, bend or wiggle the yellow cap to pull it off.
 - Never put the yellow cap back on. It may damage the needle.
 - **Do not** put your finger inside the cream safety guard.
 - It is normal to see a drop of medicine at the end of the needle or cream safety guard.



4b Pinch the skin to create a firm surface at the injection site. Place the cream safety guard straight against the pinched skin.

- Keep the skin **pinched** until the injection is finished.
- Make sure you can see the window.
- Make sure the autoinjector is positioned straight on the injection site (at a 90-degree angle).

PUSH and hold against skin



- 4c Firmly push the autoinjector down until the cream safety guard stops moving. Hold the autoinjector down, do not lift.
 - The cream safety guard pushes in and unlocks the light blue start button.

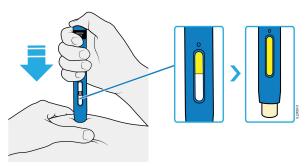
PRESS light blue start button



4d Keep pushing the autoinjector down and press the light blue start button to start the injection.

- You may hear or feel a click.
- The window starts to turn yellow.
- It is okay to let go of the light blue start button.

WATCH and CONFIRM that the window turns fully yellow



4e Keep pushing the autoinjector down. When the window is fully yellow, the injection is complete.

- The injection may take up to 10 seconds to complete.
- You may hear or feel a click.
- Lift the autoinjector away from your skin.
- The cream safety guard locks around the needle.

Important: If the window has not turned fully yellow, or it looks like the medicine is still coming out, you have not received a full dose. Call your healthcare provider right away.

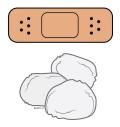
5. Disposing of AMJEVITA and Checking the Injection Site



5a Place the used autoinjector and yellow cap in an FDA-cleared sharps disposal container right away after use.

Important: Do not throw away the autoinjector in your household trash.

- **Do not** reuse the autoinjector.
- **Do not** touch the cream safety guard.



5b Check the injection site.

- **Do not** rub the injection site.
- If there is blood, press a cotton ball or gauze pad on your injection site. Apply an adhesive bandage if necessary.

Additional information about your sharps disposal container

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.

Disposing of sharps disposal containers:

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 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.

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

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

AMJEVITA (adalimumab-atto)



Manufactured by: Amgen Inc. One Amgen Center Drive Thousand Oaks, California 91320-1799 US License Number 1080 ©2023 Amgen Inc. All rights reserved. nnnnnnnn Issued: 8/2023

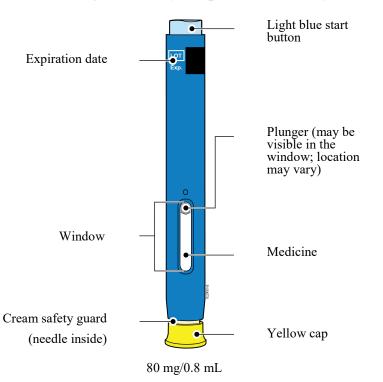
INSTRUCTIONS FOR USE AMJEVITA[™] (am-jeh-vee'-tah) (adalimumab-atto) injection, for subcutaneous use 80 mg/0.8 mL single-dose prefilled SureClick[®] autoinjector

This Instructions for Use contains information on how to inject AMJEVITA with a SureClick autoinjector.

If your healthcare provider 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 healthcare provider or nurse.

The medicine in the AMJEVITA autoinjector is for injection under the skin (subcutaneous injection). See the AMJEVITA Medication Guide for information about AMJEVITA.

Getting to know your prefilled autoinjector



1. Important Information You Need to Know Before Injecting AMJEVITA

- It is important that you do not try to give the injection until you have fully read and understood this Instructions for Use.
- **Do not** use the autoinjector if the carton is damaged or the seal is broken.
- **Do not** use the autoinjector after the expiration date on the label.
- **Do not** shake the autoinjector.
- Do not remove the yellow cap from the autoinjector until you are ready to inject.
- **Do not** use the autoinjector if it has been frozen.
- **Do not** use the autoinjector if it has been dropped on a hard surface. Part of the autoinjector may be broken even if you cannot see the break. Use a new autoinjector, and call 1-800-77-AMGEN (1-800-772-6436).
- The autoinjector is not made with natural rubber latex.

Important: Keep the autoinjector and sharps disposal container out of the sight and reach of children.

Frequently asked questions:

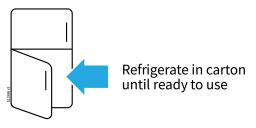
For additional information and answers to frequently asked questions, visit www.amjevita.com.

Where to get help:

If you want more information or help using AMJEVITA:

- Contact your healthcare provider,
- Visit www.amjevita.com, or
- Call 1-800-77-AMGEN (1-800-772-6436)

2. Storing and Preparing to Inject AMJEVITA



2a Refrigerate the autoinjector carton until you are ready to use it.

- Keep the autoinjector in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the autoinjector in the original carton to protect it from light or physical damage.
- **Do not** freeze the autoinjector.
- **Do not** store the autoinjector in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.

Important: Keep the autoinjector out of the sight and reach of children.



2b Wait 15 to 30 minutes for the autoinjector to reach room temperature.

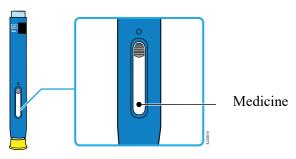
- Remove the number of autoinjectors you need for your injection and put any unused autoinjectors back into the refrigerator.
- Let the autoinjector warm up naturally.
- Do not heat the autoinjector with hot water, a microwave, or direct sunlight.
- **Do not** shake the autoinjector at any time.
- Using the autoinjector at room temperature makes sure the full dose is delivered and allows for a more comfortable injection.



You may keep AMJEVITA at room temperature for up to 14 days, if needed. **2c**

- For example, when you are traveling, you may keep AMJEVITA at room temperature. •
 - 0 Keep it at room temperature between 68°F to 77°F (20°C to 25°C).
 - Do not put it back in the refrigerator. 0
 - Record the date you removed it from the refrigerator and use it within 14 days. 0

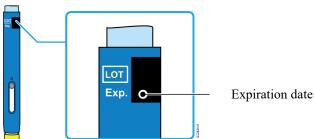
Important: Place the autoinjector in a sharps disposal container if it has reached room temperature and has not been used within 14 days.



Inspect the medicine. It should be clear and colorless to pale vellow. 2d

- It is okay to see air bubbles in the autoinjector.
- Do not use AMJEVITA if the medicine is cloudy, discolored, or has flakes or particles.

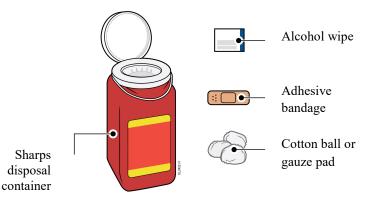
Important: If the medicine is cloudy, discolored, or has flakes or particles, or if the autoinjector is damaged or expired, call 1-800-77-AMGEN (1-800-772-6436).



2e Check the expiration date (Exp.) and inspect the autoinjector for damage.

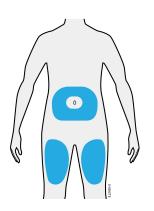
- Do not use the autoinjector if the expiration date has passed. •
- **Do not** use the autoinjector if:
 - 0 the yellow cap is missing or loose.
 - it has cracks or broken parts. 0
 - it has been dropped on a hard surface. 0
- Make sure you have the right medicine and dose.

3. Getting Ready for Your Injection



3a Gather and place the following items for your injection on a clean, flat, and well-lit surface:

- AMJEVITA autoinjector (room temperature)
- Sharps disposal container [see Disposing of AMJEVITA and Checking the Injection Site]
- Alcohol wipe
- Adhesive bandage
- Cotton ball or gauze pad



3b Inject into 1 of these locations.

- Inject into the front of your thigh or stomach (except for 2 inches around your belly button).
- Choose a different site for each injection.

Important: Avoid areas with scars or stretch marks, or where the skin is tender, bruised, red, or hard.



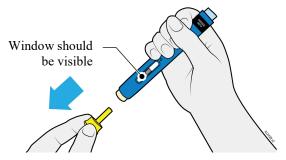
3c Wash hands thoroughly with soap and water.



- 3d Clean the injection site with an alcohol wipe.
 - Let the skin dry on its own.
 - **Do not** touch this area again before injecting.

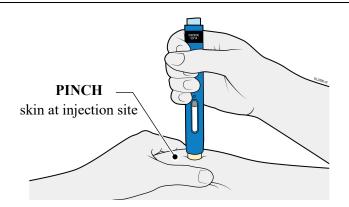
4. Injecting AMJEVITA

Important: Only remove the yellow cap when you can inject right away (within 5 minutes) because the medicine can dry out. **Do not** recap.



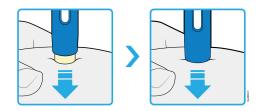
4a Grasp the autoinjector so you can see the window. Pull the yellow cap straight off. You may need to pull hard.

- **Do not** twist, bend or wiggle the yellow cap to pull it off.
- Never put the yellow cap back on. It may damage the needle.
- **Do not** put your finger inside the cream safety guard.
- It is normal to see a drop of medicine at the end of the needle or cream safety guard.



- **4b** Pinch the skin to create a firm surface at the injection site. Place the cream safety guard straight against the pinched skin.
 - Keep the skin **pinched** until the injection is finished.
 - Make sure you can see the window.
 - Make sure the autoinjector is positioned straight on the injection site (at a 90-degree angle).

PUSH and hold against skin



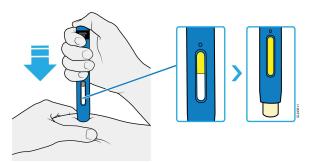
- 4c Firmly push the autoinjector down until the cream safety guard stops moving. Hold the autoinjector down, do not lift.
 - The cream safety guard pushes in and unlocks the light blue start button.



4d Keep pushing the autoinjector down and press the light blue start button to start the injection.

- You may hear or feel a click.
- The window starts to turn yellow.
- It is okay to let go of the light blue start button.

WATCH and CONFIRM that the window turns fully yellow



4e Keep pushing the autoinjector down. When the window is fully yellow, the injection is complete.

- The injection may take up to 15 seconds to complete.
- You may hear or feel a click.
- Lift the autoinjector away from your skin.
- The cream safety guard locks around the needle.

Important: If the window has not turned fully yellow, or it looks like the medicine is still coming out, you have not received a full dose. Call your healthcare provider right away.

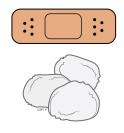
5. Disposing of AMJEVITA and Checking the Injection Site



5a Place the used autoinjector and yellow cap in an FDA-cleared sharps disposal container right away after use.

Important: Do not throw away the autoinjector in your household trash.

- **Do not** reuse the autoinjector.
- **Do not** touch the cream safety guard.



5b Check the injection site.

- **Do not** rub the injection site.
- If there is blood, press a cotton ball or gauze pad on your injection site. Apply an adhesive bandage if necessary.

Additional information about your sharps disposal container

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.

Disposing of sharps disposal containers:

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 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.

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

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

AMJEVITA (adalimumab-atto)



Manufactured by: Amgen Inc. One Amgen Center Drive Thousand Oaks, California 91320-1799 US License Number 1080 ©2023 Amgen Inc. All rights reserved. nnnnnnnn Issued: 8/2023

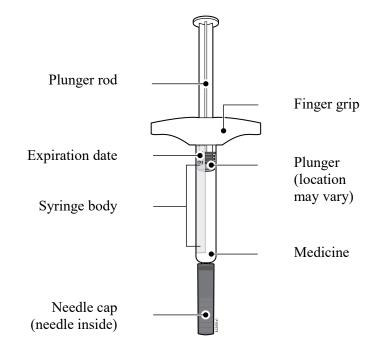
INSTRUCTIONS FOR USE AMJEVITA[™] (am-jeh-vee'-tah) (adalimumab-atto) injection, for subcutaneous use 20 mg/0.2 mL 40 mg/0.4 mL 80 mg/0.8 mL single-dose prefilled syringe

This Instructions for Use contains information on how to inject AMJEVITA with a prefilled syringe.

If your healthcare provider 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 healthcare provider or nurse.

The medicine in the AMJEVITA prefilled syringe is for injection under the skin (subcutaneous injection). See the AMJEVITA Medication Guide for information about AMJEVITA.

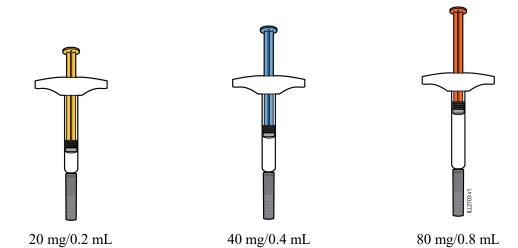
Getting to know your prefilled syringe



1. Important Information You Need to Know Before Injecting AMJEVITA

Dosing:

- AMJEVITA comes in 3 different doses: 20 mg/0.2 mL, 40 mg/0.4 mL, and 80 mg/0.8 mL. Check your prescription to make sure you have the correct dose.
- The color and look of the prefilled syringe will be different for each dose. The amount of medicine in the syringe will also be different for each dose.
- For example, it is okay for the 20 mg/0.2 mL dose to have a small amount of medicine and the 80 mg/0.8 mL to have a large amount of medicine. Check the illustrations below to see what your dose looks like in the syringe.



- It is important that you do not try to give the injection until you have fully read and understood this Instructions for Use.
- **Do not** use the syringe if the carton is damaged or the seal is broken.
- **Do not** use the syringe after the expiration date on the label.
- **Do not** shake the syringe.
- **Do not** remove the needle cap from the syringe until you are ready to inject.
- **Do not** use the syringe if it has been frozen.
- **Do not** use the syringe if it has been dropped on a hard surface. Part of the syringe may be broken even if you cannot see the break. Use a new syringe, and call 1-800-77-AMGEN (1-800-772-6436).
- The syringe is not made with natural rubber latex.

Important: Keep the syringe and sharps disposal container out of the sight and reach of children.

Frequently asked questions:

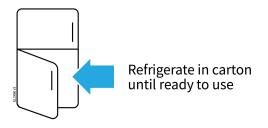
For additional information and answers to frequently asked questions, visit www.amjevita.com.

Where to get help:

If you want more information or help using AMJEVITA:

- Contact your healthcare provider,
- Visit www.amjevita.com, or
- Call 1-800-77-AMGEN (1-800-772-6436)

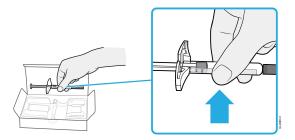
2. Storing and Preparing to Inject AMJEVITA



2a Refrigerate the syringe carton until you are ready to use it.

- Keep the syringe in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the syringe in the original carton to protect it from light or physical damage.
- **Do not** freeze the syringe.
- **Do not** store the syringe in extreme heat or cold. For example, avoid storing in your vehicle's glove box or trunk.

Important: Keep the syringe out of the sight and reach of children.



2b Grasp the syringe by the body and remove it from the carton.

- **Do not** grab the finger grip, plunger rod, or the needle cap.
- Remove the number of syringes you need for your injection.
- Put any unused syringes back into the refrigerator.



2c Wait 15 to 30 minutes for the syringe to reach room temperature.

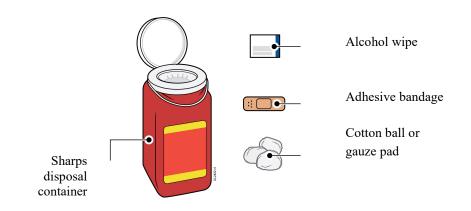
- Let the syringe warm up naturally.
- Do not heat the syringe with hot water, a microwave, or direct sunlight.
- **Do not** shake the syringe at any time.
- Using the syringe at room temperature allows for a more comfortable injection.



2d You may keep AMJEVITA at room temperature for up to 14 days, if needed.

- For example, when you are traveling, you may keep AMJEVITA at room temperature.
 - o Keep it at room temperature between 68°F to 77°F (20°C to 25°C).
 - o **Do not** put it back in the refrigerator.
 - o Record the date you removed it from the refrigerator and use it within 14 days.

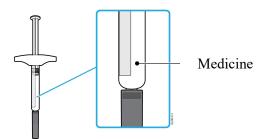
Important: Place the syringe in a sharps disposal container if it has reached room temperature and has not been used within 14 days.



2e Gather and place the following items for your injection on a clean, flat, and well-lit surface:

- AMJEVITA syringe (room temperature)
- Sharps disposal container [see Disposing of AMJEVITA and Checking the Injection Site]
- Alcohol wipe
- Adhesive bandage
- Cotton ball or gauze pad

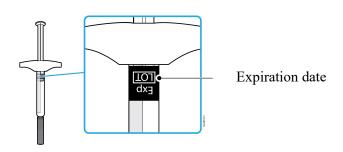
3. Getting Ready for Your Injection



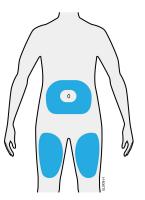
3a Inspect the medicine. It should be clear and colorless to pale yellow.

- It is okay to see air bubbles in the syringe.
- **Do not** use AMJEVITA if the medicine is cloudy, discolored, or has flakes or particles.

Important: If the medicine is cloudy, discolored, or has flakes or particles, or if the syringe is damaged or expired, call 1-800-77-AMGEN (1-800-772-6436).



- **3b** Check the expiration date (Exp.) and inspect the syringe for damage.
 - **Do not** use the syringe if the expiration date has passed.
 - **Do not** use the syringe if:
 - the needle cap is missing or loose.
 - \circ it has cracks or broken parts.
 - it has been dropped on a hard surface.
 - Make sure you have the right medicine and dose.



3c Inject into 1 of these locations.

- Inject into the front of your thigh or stomach (except for 2 inches around your belly button).
- Choose a different site for each injection.

Important: Avoid areas with scars or stretch marks, or where the skin is tender, bruised, red, or hard.



3d

Wash hands thoroughly with soap and water.

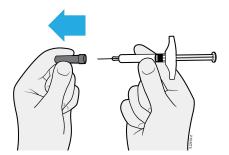


3e Clean the injection site with an alcohol wipe.

- Let the skin dry on its own.
- **Do not** touch this area again before injecting.

4. Injecting AMJEVITA

Important: Only remove the needle cap when you can inject right away (within 5 minutes) because the medicine can dry out. **Do not** recap.



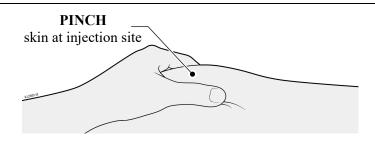
4a Pull the needle cap straight off while holding the syringe body.

- **Do not** twist or bend the needle cap.
- Never put the needle cap back on. It may damage the needle.
- **Do not** let anything touch the needle after you remove the needle cap.
- **Do not** place the uncapped syringe on any surface after you remove the needle cap.
- **Do not** try to push air bubbles out of the syringe. It is okay to see air bubbles.
- It is normal to see a drop of medicine come out of the needle.

Important: Never put the needle cap back on to avoid accidental needlestick injury.



4b Place the needle cap in the sharps disposal container.

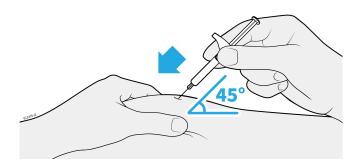


4c

Pinch the skin around the injection site before injection.

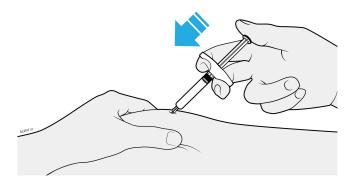
- Pinch the skin between the thumb and pointer (index) finger to create a bump for the injection.
- If possible, the bump should be about 2 inches wide.

Important: Continue to pinch the skin until the injection is complete.



- 4d Insert the needle into the pinched skin at a 45-degree angle.
 - **Do not** place your finger on the plunger rod while inserting the needle, as this may result in lost medicine.

INJECT



4e Slowly press the plunger rod all the way down until it reaches the bottom of the syringe to inject the medicine.

- **Do not** pull back on the plunger rod at any time.
- **Do not** remove the syringe until all of the medicine has been injected.

5. Disposing of AMJEVITA and Checking the Injection Site

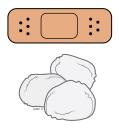
Important: Never put the needle cap back on.



5a Place the used syringe in an FDA-cleared sharps disposal container right away after use.

Important: Do not throw away the syringe in your household trash.

• **Do not** reuse the syringe.



5b Check the injection site.

- **Do not** rub the injection site.
- If there is blood, press a cotton ball or gauze pad on your injection site. Apply an adhesive bandage if necessary.

Additional information about your sharps disposal container

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.

Disposing of sharps disposal containers:

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 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.

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

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

AMJEVITA (adalimumab-atto)



Manufactured by: Amgen Inc. One Amgen Center Drive Thousand Oaks, California 91320-1799 US License Number 1080 ©2023 Amgen Inc. All rights reserved. nnnnnnnn Issued: 8/2023