

Instructions for Use
ACTEMRA® (AC-TEM-RA)
(tocilizumab)
Injection, For Subcutaneous Use
Single-dose Prefilled Syringe

Read and follow the Instructions for Use that come with your ACTEMRA prefilled syringe before you start using it and each time you get a prescription refill. Before you use ACTEMRA prefilled syringe for the first time, make sure your healthcare provider shows you the right way to use it.

- **Do not remove the needle cap until you are ready to inject ACTEMRA.**
- **Do not try to take apart the syringe at any time.**
- **Do not reuse the same syringe.**

Parts of your ACTEMRA Prefilled Syringe (See Figure A).

Pre-filled Syringe parts

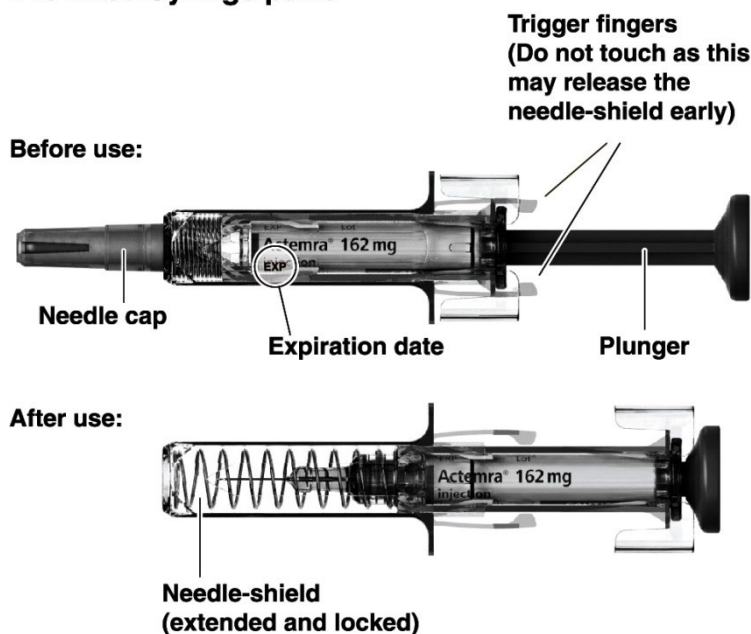


Figure A

Supplies needed for your ACTEMRA Prefilled Syringe Injection (See Figure B):

- ACTEMRA prefilled syringe
- alcohol pad
- sterile cotton ball or gauze
- puncture-resistant container or sharps container for safe disposal of needle cap and used syringe (**See Step 4 “Dispose of the syringe”**)

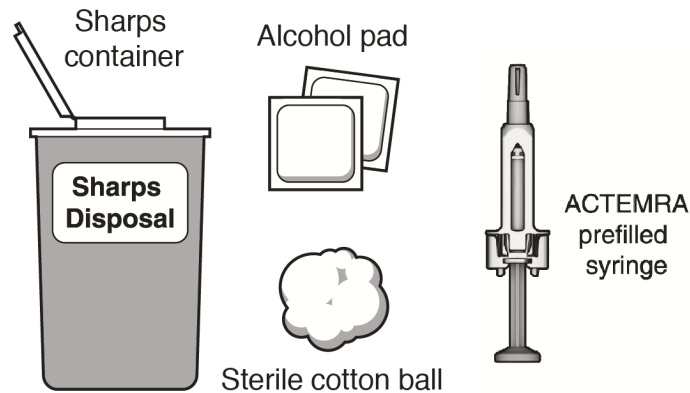


Figure B

Step 1. Preparing for an ACTEMRA Injection

Find a comfortable space with a clean, flat, working surface.

- Take the box containing the syringe out of the refrigerator and open the box. **Do not** touch the trigger fingers on the syringe as this may damage the syringe.
- Remove 1 single-use ACTEMRA prefilled syringe from the box and let it warm up for 30 minutes to allow it to reach room temperature. If the syringe does not reach room temperature, this could cause your injection to feel uncomfortable and make it difficult to push the plunger in.
- **Do not** speed up the warming process in any way, such as using the microwave or placing the syringe in warm water.
- Check the expiration date on the ACTEMRA prefilled syringe (**See Figure A**). **Do not** use it if the expiration date has passed because it may not be safe to use. If the expiration date has passed safely dispose of the syringe in a sharps container and get a new one.

Do not remove the needle cap while allowing your ACTEMRA prefilled syringe to reach room temperature.

- Keep your unused syringes in the original carton and keep in the refrigerator at 36°F to 46°F (2°C to 8°C). **Do not** freeze.
- Once removed from the refrigerator, your prefilled syringe can be stored up to 2 weeks at or below 86°F (30°C). Your prefilled syringe must always be kept in the original carton in order to protect from light and moisture. Hold your ACTEMRA prefilled syringe with the covered needle pointing down (**See Figure C**).

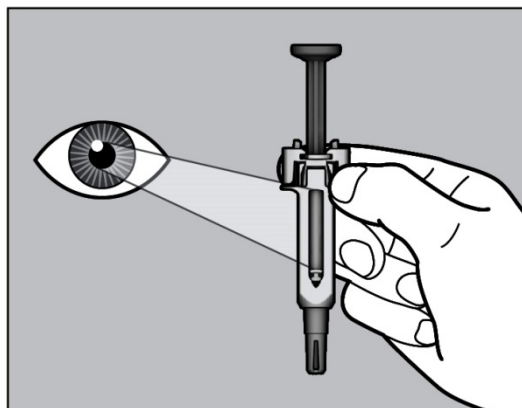


Figure C

- Check the liquid in the ACTEMRA prefilled syringe. It should be clear and colorless to pale yellow. Do not inject ACTEMRA if the liquid is cloudy, discolored, or has lumps or particles in it because it may not be safe to use. Safely dispose of the syringe in a sharps container and get a new one.
- Wash your hands well with soap and water.

Step 2. Choose and Prepare an Injection Site

Choose an Injection Site

- The front of your thigh and your abdomen except for the 2-inch area around your navel are the recommended injection sites (**See Figure D**).
- The outer area of the upper arms may also be used only if the injection is being given by a caregiver. Do not attempt to use the upper arm area by yourself (**See Figure D**).

Rotate Injection Site

- Choose a different injection site for each new injection at least 1-inch from the last area you injected.
- Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard or not intact.

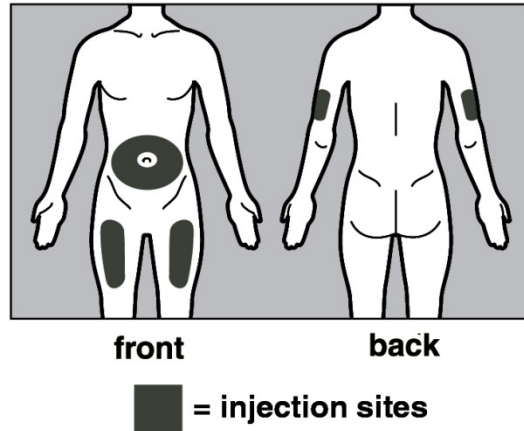


Figure D

Prepare the Injection Site

- Wipe the injection site with an alcohol pad in a circular motion and let it air dry to reduce the chance of getting an infection. **Do not** touch the injection site again before giving the injection.
- **Do not** fan or blow on the clean area.

Step 3. Inject ACTEMRA

- Hold the ACTEMRA prefilled syringe with 1 hand and pull the needle cap straight off with your other hand (**See Figure E**). **Do not** hold the plunger while you remove the needle cap. If you cannot remove the needle cap you should ask a caregiver for help or contact your healthcare provider.

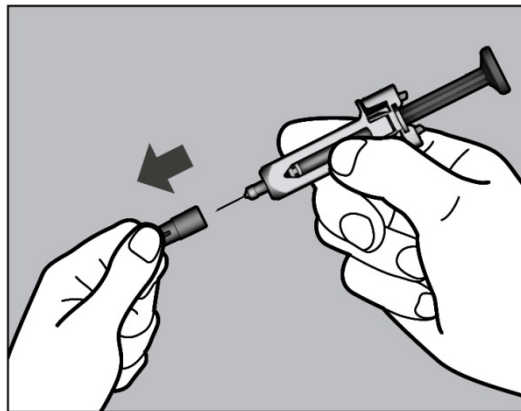


Figure E

- Throw away the needle cap in a sharps container.

- There may be a small air bubble in the ACTEMRA prefilled syringe. You do not need to remove it.
- You may see a drop of liquid at the end of the needle. This is normal and will not affect your dose.
- **Do not** touch the needle or let it touch any surfaces.
- **Do not** use the prefilled syringe if it is dropped.
- If it is not used within 5 minutes of needle cap removal, the syringe should be disposed of in the puncture resistant container or sharps container and a new syringe should be used.
- Never reattach the needle cap after removal.
- Hold the ACTEMRA prefilled syringe in 1 hand between the thumb and index finger (**See Figure F**).

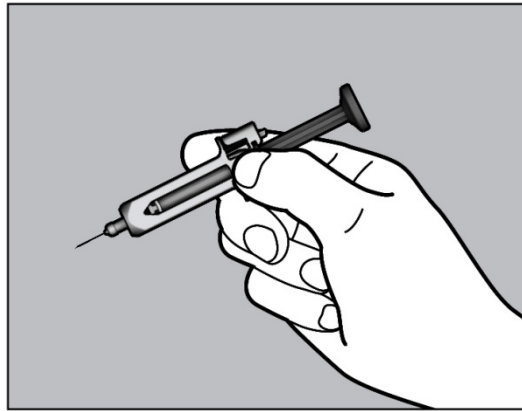


Figure F

- **Do not** pull back on the plunger of the syringe.
- Use your other hand and gently pinch the area of skin you cleaned. Hold the pinched skin firmly. Pinching the skin is important to make sure that you inject under the skin (into fatty tissue) but not any deeper (into muscle). Injection into muscle could cause the injection to feel uncomfortable.
- **Do not** hold or push on the plunger while inserting the needle into the skin.
- Use a quick, dart-like motion to insert the needle all the way into the pinched skin at an angle between 45° to 90° (**See Figure G**). It is important to use the correct angle to make sure the medicine is delivered under the skin (into fatty tissue), or the injection could be painful and the medicine may not work.

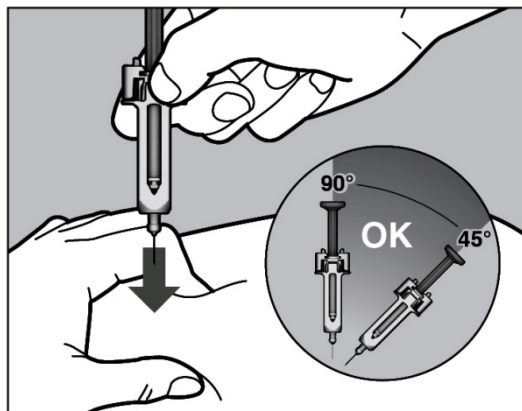


Figure G

- Keep the syringe in position and let go of the pinch of skin.
- Slowly inject all of the medicine by gently pushing the plunger all the way down (**See Figure H**). You must press the plunger all the way down to get the full dose of medicine and to ensure the trigger fingers are completely pushed to the side. If the plunger is not fully depressed the needle shield will not extend to cover the needle when it is removed. If the needle is not covered, carefully place the syringe into the puncture resistant container to avoid injury with the needle.

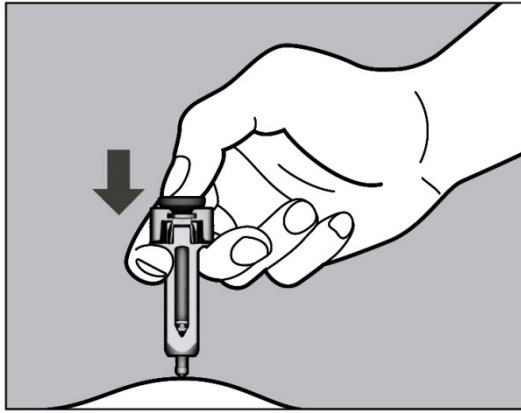


Figure H

- After the plunger is pushed all the way down, keep pressing down on the plunger to be sure all of the medicine is injected before taking the needle out of the skin.
- Keep pressing down on the plunger while you take the needle out of the skin at the same angle as inserted (**See Figure I**).

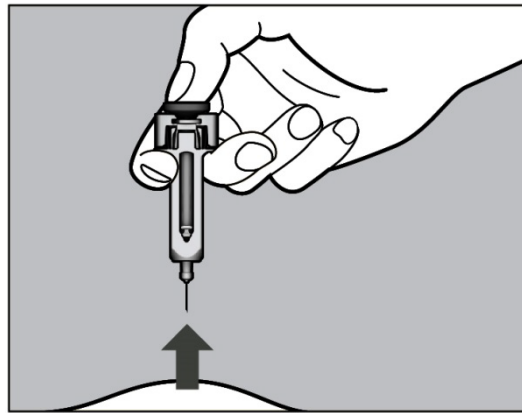


Figure I

- After the needle is removed completely from the skin, release the plunger, allowing the needle-shield to protect the needle (**See Figure J**).

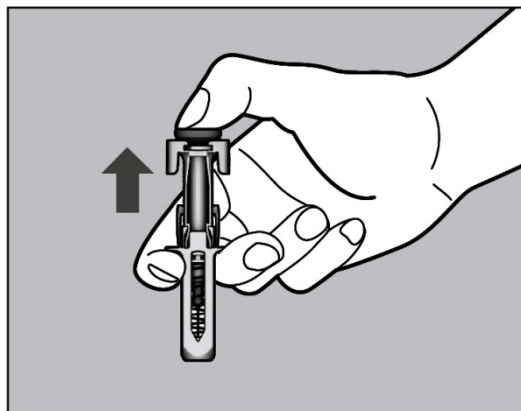


Figure J

After the Injection

- There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site.
- **Do not** rub the injection site.
- If needed, you may cover the injection site with a small bandage.

Step 4. Dispose of the syringe

- The ACTEMRA prefilled syringe should not be reused.
- Put the used syringe into your puncture resistant container (See “How do I throw away used syringes?”)
- **Do not** put the needle cap back on the needle.
- **If your injection is given by another person, this person must also be careful when removing the syringe and disposing of the syringe to prevent accidental needle stick injury and passing infection.**

How do I throw away used syringes?

- Put your used needles and syringes including ACTEMRA in a FDA-cleared sharps disposal container right away after use (See Figure K). **Do not throw away (dispose of) loose needles and syringes in your household trash.**

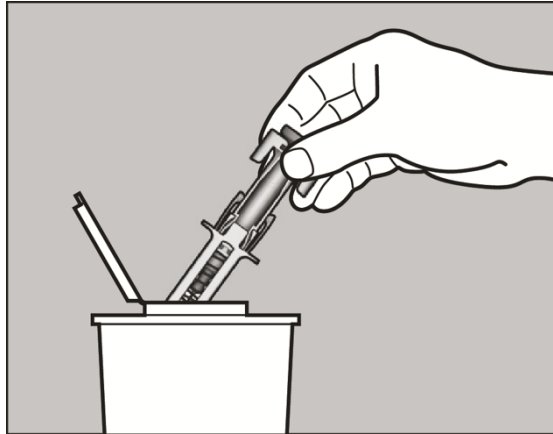


Figure K

- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - upright stable during use
 - leak-resistant
 - 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 the 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.
- **Keep ACTEMRA prefilled syringes and the disposal container out of the reach of children.**

Record your Injection

- Write the date, time, and specific part of your body where you injected yourself. It may also be helpful to write any questions or concerns about the injection so you can ask your healthcare provider.

If you have questions or concerns about your ACTEMRA prefilled syringe, please contact your healthcare provider familiar with ACTEMRA or call 1-800-ACTEMRA.

This Medication Guide and Instructions for Use has been approved by the U.S. Food and Drug Administration.
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Instructions for Use
ACTEMRA® (AC-TEM-RA)
(tocilizumab)
Injection, For Subcutaneous Use
Single-dose Prefilled ACTPen® (AKT-PEN) Autoinjector

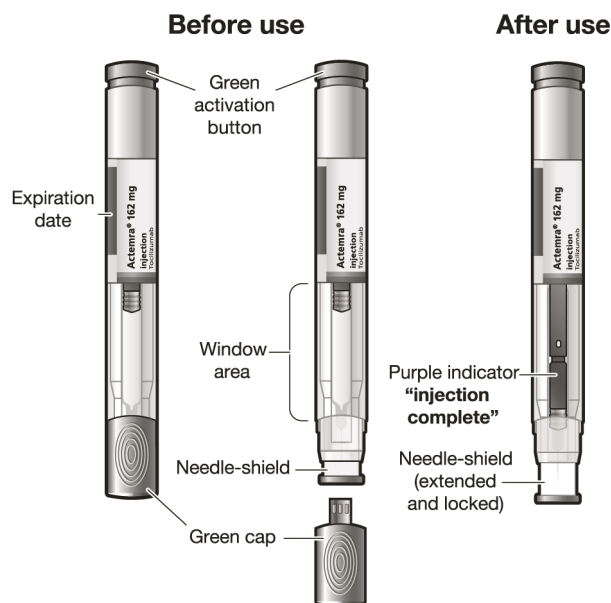
Read and follow the Instructions for Use that come with your ACTEMRA ACTPen autoinjector before you start using it and each time you get a prescription refill. Before you use the ACTEMRA ACTPen autoinjector for the first time, make sure your healthcare provider shows you the right way to use it.

Important: Keep your unused Autoinjectors in the original carton and keep in the refrigerator at 36°F to 46°F (2°C to 8°C). **Do not** freeze. Once removed from the refrigerator, your Autoinjector can be stored up to 2 weeks at or below 86°F (30°C). Your Autoinjector must always be kept in the original carton in order to protect from light and moisture.

- **Do not** remove the Autoinjector cap until you are ready to inject ACTEMRA.
- **Do not** try to take apart the Autoinjector at any time.
- **Do not** reuse the same Autoinjector.
- **Do not** use the Autoinjector through clothing.
- **Do not** leave the Autoinjector unattended.
- **Do not** use the Autoinjector if it appears to be damaged or if you have accidentally dropped the Autoinjector.
- Keep out of the reach of children.

Parts of your ACTEMRA ACTPen autoinjector (See Figure A).

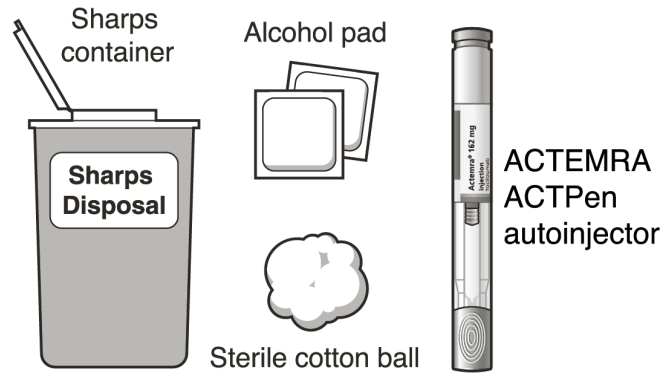
Figure A



Supplies needed for an injection using your ACTEMRA ACTPen autoinjector (See Figure B):

- 1 ACTEMRA ACTPen autoinjector
- 1 Alcohol pad
- 1 Sterile cotton ball or gauze
- 1 Puncture-resistant container or sharps container for safe disposal of Autoinjector cap and used Autoinjector (See Step 4 "Dispose of the Autoinjector")

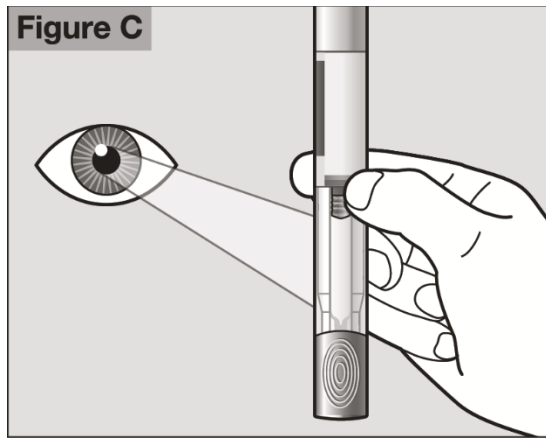
Figure B



Step 1. Preparing for an ACTEMRA Injection

Find a comfortable space with a clean, flat, working surface.

- Take the box containing the Autoinjector out of the refrigerator.
- If you are opening the box for the first time, check to make sure that it is properly sealed. **Do not** use the Autoinjector if the box looks like it has already been opened.
- Check that the Autoinjector box is not damaged. **Do not** use ACTEMRA ACTPen autoinjector if the box looks damaged.
- **Check the expiration date on the Autoinjector box.** **Do not** use the Autoinjector if the expiration date has passed because it may not be safe to use.
- Open the box, and remove 1 single-use ACTEMRA ACTPen autoinjector from the box.
- Return any remaining autoinjectors in the box to the refrigerator.
- **Check the expiration date on the ACTEMRA ACTPen autoinjector (See Figure A).** **Do not** use it if the expiration date has passed because it may not be safe to use. If the expiration date has passed, safely dispose of the Autoinjector in a sharps container and get a new one.
- **Check the Autoinjector to make sure it is not damaged.** **Do not** use the Autoinjector if it appears to be damaged or if you have accidentally dropped the Autoinjector.
- Place the Autoinjector on a clean, flat surface and let the Autoinjector warm up for 45 minutes to allow it to reach room temperature. If the Autoinjector does not reach room temperature, this could cause your injection to feel uncomfortable and it could take longer to inject.
 - **Do not** speed up the warming process in any way, such as using the microwave or placing the Autoinjector in warm water.
 - **Do not** leave the Autoinjector to warm up in direct sunlight.
 - **Do not** remove the green cap while allowing your ACTEMRA ACTPen autoinjector to reach room temperature.
- Hold your ACTEMRA ACTPen autoinjector with the green cap pointing down (**See Figure C**).
- Look in the clear Window area. Check the liquid in the ACTEMRA ACTPen autoinjector (**See Figure C**). It should be clear and colorless to pale yellow. **Do not** inject ACTEMRA if the liquid is cloudy, discolored, or has lumps or particles in it because it may not be safe to use. Safely dispose of the Autoinjector in a sharps container and get a new one.



- Wash your hands well with soap and water.

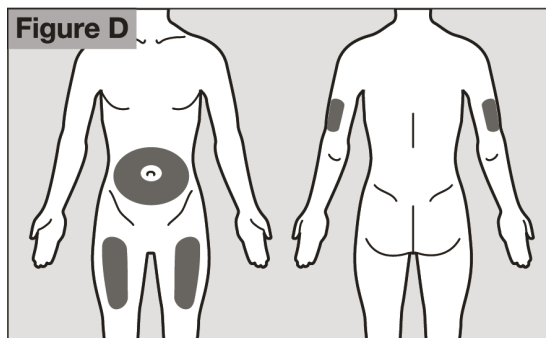
Step 2. Choose and Prepare an Injection Site

Choose an Injection Site

- The front of your thigh or your abdomen except for the 2-inch (5cm) area around your navel are the recommended injection sites (**See Figure D**).
- The outer area of the upper arms may also be used only if the injection is being given by a caregiver. **Do not** attempt to use the upper arm area by yourself (**See Figure D**).

Rotate Injection Site

- Choose a different injection site for each new injection at least 1 inch (2.5cm) from the last area you injected.
- **Do not** inject into moles, scars, bruises, or areas where the skin is tender, red, hard or not intact.



Front

Back

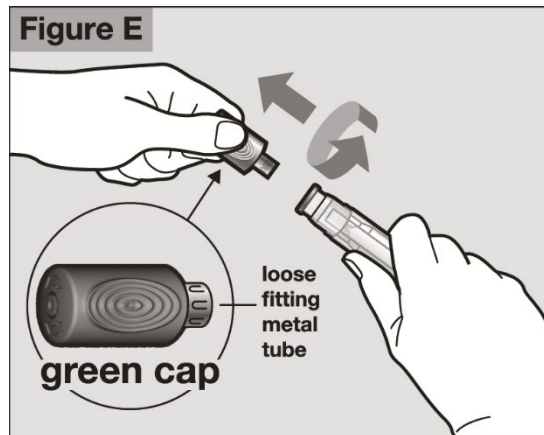
■ = injection sites

Prepare the Injection Site

- Wipe the injection site with an alcohol pad in a circular motion and let it air dry to reduce the chance of getting an infection. **Do not** touch the injection site again before giving the injection.
- **Do not** fan or blow on the clean area.

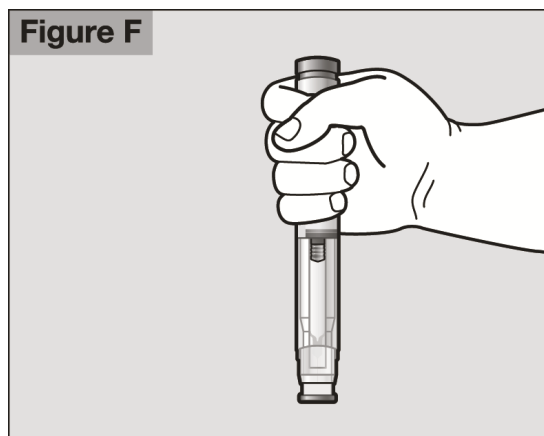
Step 3. Inject ACTEMRA

- Hold the ACTEMRA ACTPen autoinjector firmly with one hand. Twist and pull off the green cap with the other hand (**See Figure E**). The green cap contains a loose fitting metal tube.
- If you cannot remove the green cap you should ask a caregiver for help or contact your healthcare provider.

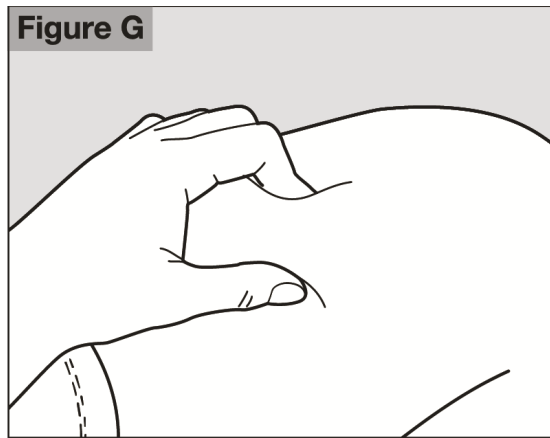


Important: Do not touch the needle shield which is located at the tip of the Autoinjector below the Window area (See Figure A), to avoid accidental needle stick injury.

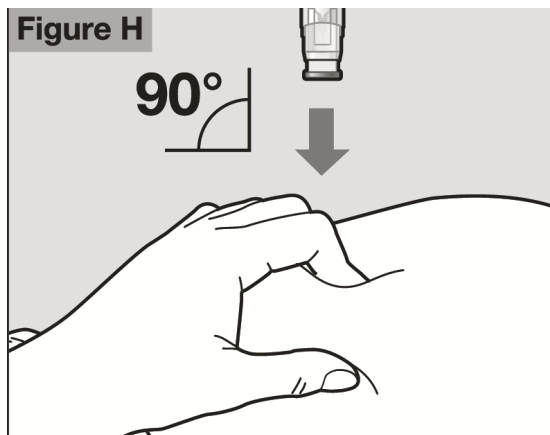
- Throw away the green cap in a sharps container.
- After you remove the green cap, the Autoinjector is ready for use. **If the Autoinjector is not used within 3 minutes of the cap removal, the Autoinjector should be disposed of in the sharps container and a new Autoinjector should be used.**
- Never reattach the green cap after removal.
- Hold the Autoinjector comfortably in 1 hand by the upper part, so that you can see the Window area of the Autoinjector (**See Figure F**).



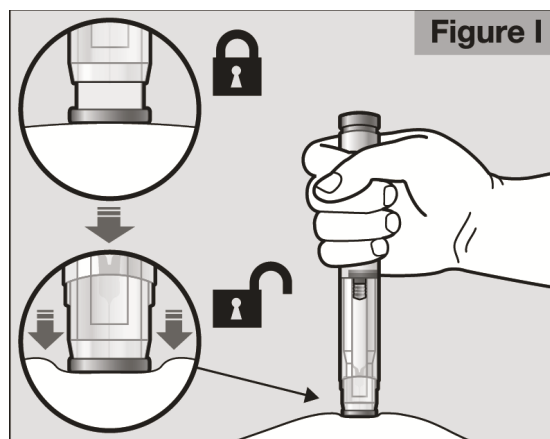
- Use your other hand to gently pinch the area of skin you cleaned, to prepare a firm injection site (**See Figure G**). The Autoinjector requires a firm injection site to properly activate. Pinching the skin is important to make sure that you inject under the skin (into fatty tissue) but not any deeper (into muscle). Injection into muscle could cause the injection to feel uncomfortable.



- **Do not** press the green Activation button yet.
Place the needle-shield of the Autoinjector against your pinched skin at a 90° angle (**See Figure H**).
- It is important to use the correct angle to make sure the medicine is delivered under the skin (into fatty tissue), or the injection could be painful and the medicine may not work.
- **Continue to gently pinch throughout the injection procedure.**

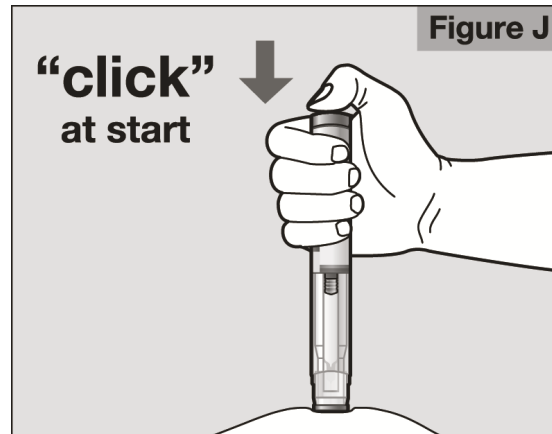


- To use the Autoinjector, you first have to unlock the green Activation button. To unlock it, press the Autoinjector firmly against your pinched skin until the needle-shield is completely pushed in (**See Figure I**).

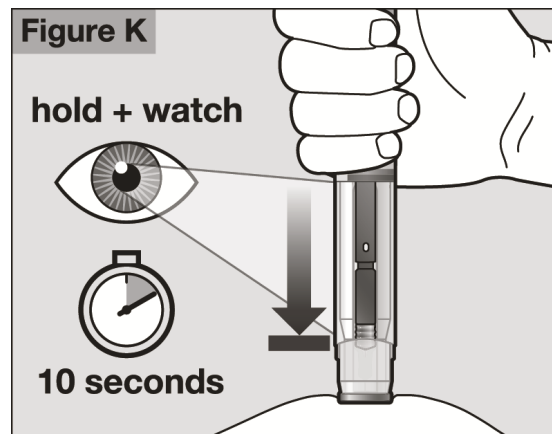


- Continue to keep the needle-shield pushed in. If you do not keep the needle-shield completely pushed against the skin, the green Activation button will not work. Continue to pinch the skin while you keep the Autoinjector in place.

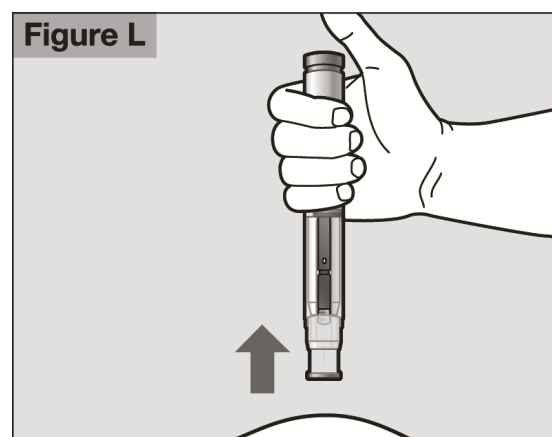
- Press the green Activation button to start the injection. A “click” sound indicates the **start** of the injection. Keep the green button pressed in and continue holding the Autoinjector pressed firmly against your skin (**See Figure J**). If you cannot start the injection you should ask for help from a caregiver or contact your healthcare provider.



- The purple indicator will move along the Window area during the injection (**See Figure K**).
- **Watch the purple indicator until it stops moving** to be sure the full dose of medicine is injected. This may take up to **10 seconds**.



- You may hear a second “click” during the injection but you should continue to hold the Autoinjector firmly against your skin until the purple indicator stops moving.
- When the purple indicator has stopped moving, release the green button. Lift the Autoinjector straight off of the injection site at a 90° angle to remove the needle from the skin. The needle-shield will then move out and lock into place covering the needle (**See Figure L**).



- Check the Window area to see that it is filled with the purple indicator (**See Figure L**).
- If the Window area is not filled by the purple indicator then:
 - The needle-shield may not have locked. **Do not** touch the needle-shield of the Autoinjector, because you may stick yourself with the needle. If the needle is not covered, carefully place the Autoinjector into the sharps container to avoid any injury with the needle.
 - You may not have received your full dose of ACTEMRA. **Do not** try to re-use the Autoinjector. **Do not** repeat the injection with another Autoinjector. Call your healthcare provider for help.

After the Injection

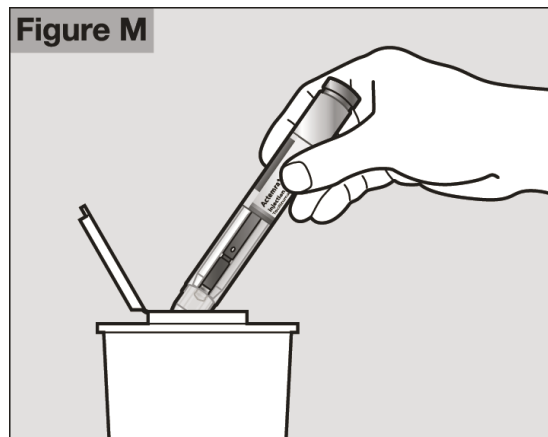
- There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site.
- **Do not** rub the injection site.
- If needed, you may cover the injection site with a small bandage.

Step 4. Dispose of the Autoinjector

- The ACTEMRA ACTPen autoinjector should not be reused.
- Put the used Autoinjector into your sharps container (**See “How do I dispose of used Autoinjectors?”**).
- **Do not** put the cap back on the Autoinjector.
- **If your injection is given by another person, this person must also be careful when removing the Autoinjector and disposing of it to prevent accidental needle stick injury and passing infection.**

How do I dispose of used Autoinjectors?

- Put your used ACTEMRA ACTPen autoinjector and green cap in a FDA-cleared sharps disposal container right away after use (**See Figure M**).
- **Do not** throw away (dispose of) the Autoinjector and the green cap in your household trash.



- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - upright stable during use
 - leak-resistant
 - 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 dispose of used Autoinjectors. For more information about the 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.

Keep the ACTEMRA ACTPen autoinjector and disposal container out of the reach of children.

Record your Injection

- Write the date, time, and specific part of your body where you injected yourself. It may also be helpful to write any questions or concerns about the injection so you can ask your healthcare provider.

If you have any questions or concerns about your ACTEMRA ACTPen autoinjector, talk to your healthcare provider familiar with ACTEMRA or call 1-800-ACTEMRA.

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

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