

For patients who have chosen the ACTPen[®] as their injection device

HOW TO INJECT WITH YOUR ACTPen

Remember, always review the FDA-approved ACTEMRA Instructions for Use prior to using the autoinjector

To help walk you through your treatment, let's get to know your ACTPen

Supplies needed for an injection:

- x1** ACTPen
- x1** Sterile cotton ball or gauze
- x1** Alcohol pad
- x1** Sharps container

What does ACTEMRA treat?

ACTEMRA is a prescription medicine used to treat:

- Adults with moderately to severely active rheumatoid arthritis (RA) after at least one other medicine called a disease modifying antirheumatic drug (DMARD) has been used and did not work well
- Adults with giant cell arteritis (GCA)
- Patients with active polyarticular juvenile idiopathic arthritis (PJIA) 2 years of age and older
- Patients with active systemic juvenile idiopathic arthritis (SJIA) 2 years of age and older

It is not known if ACTEMRA is safe and effective in children with PJIA or SJIA under 2 years of age or in children with conditions other than PJIA or SJIA.

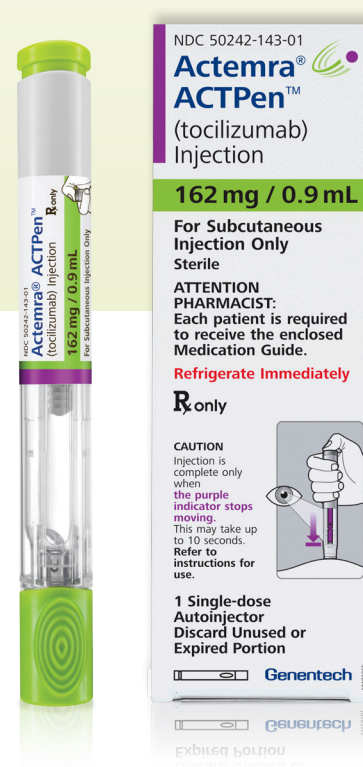
ACTEMRA can cause serious side effects

Serious Infections

ACTEMRA changes the way your immune system works. This can make you more likely to get infections or make any current infection worse. Some people have died from these infections. Your healthcare provider should test you for TB before starting and during treatment with ACTEMRA.

Do not take ACTEMRA if you are allergic to tocilizumab, or any of the ingredients in ACTEMRA.

Please see additional Important Safety Information on pages 9-10. For more Important Safety Information, please see full [Prescribing Information](#) and [Medication Guide](#), including **Serious Side Effects**.



Not actual size.

What is the ACTPen?

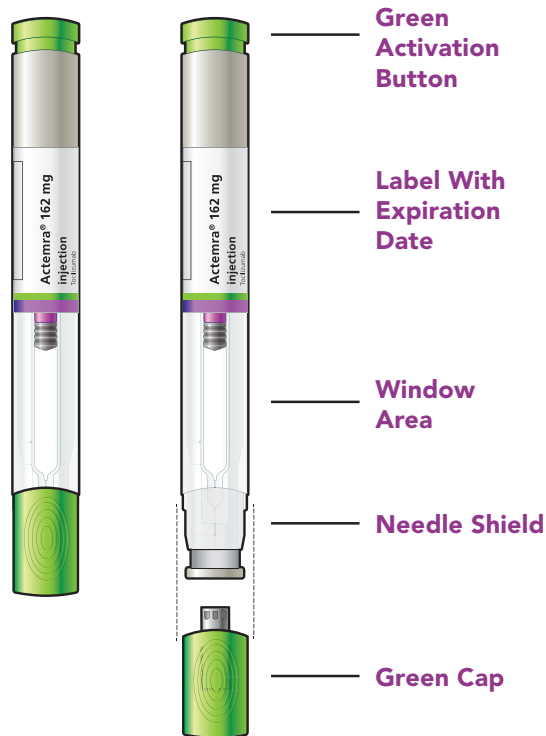
The ACTPen is a single-dose autoinjector that can help you inject ACTEMRA under the skin (subcutaneously). Read these step-by-step instructions before you start using your ACTPen and as a reminder each time you get a prescription refill. Before using your ACTPen for the first time, make sure your healthcare provider shows you the right way to use it.

Please also be sure to review the FDA-approved Instructions for Use for step-by-step directions.

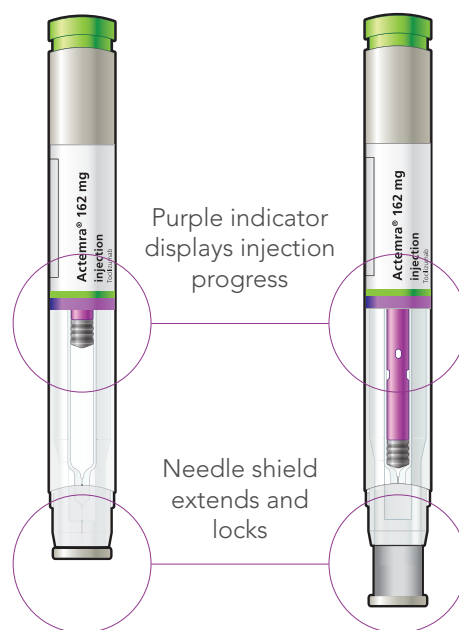
Keep in mind:

- Keep your unused ACTPens in the original carton and keep in the refrigerator at 36°F to 46°F (2°C to 8°C). **Do not** freeze
- **Do not** remove the ACTPen cap until you are ready to inject ACTEMRA
- **Do not** try to take apart the ACTPen at any time
- **Do not** reuse the same ACTPen
- **Do not** use the ACTPen through clothing
- **Do not** leave the ACTPen unattended
- Keep out of the reach of children

BEFORE USE



DURING USE



AFTER USE



For pediatric patients:

When injecting ACTEMRA subcutaneous (SC), pediatric patients may self-inject if both the healthcare provider and caregiver find it appropriate. Caregivers may inject pediatric patients with either the prefilled syringe or the ACTPen. The ability of pediatric patients to self-inject ACTEMRA with an autoinjector has not been tested.

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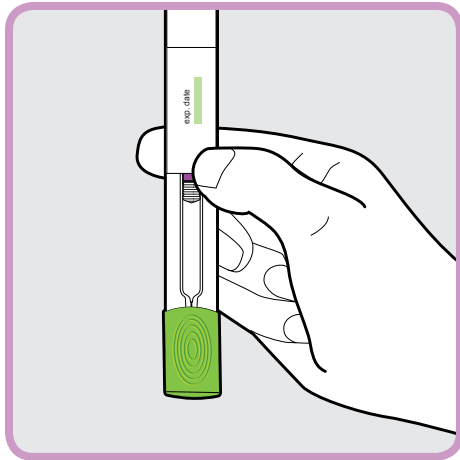


FIGURE A

1 Preparing for an ACTEMRA injection

Check box, remove ACTPen, and inspect

- Find a comfortable space with a clean and flat working surface
- Remove the box from 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 ACTPen if the box looks like it has been opened
- **Check the box for damage and expiration date**
- Take one single-use ACTPen out of the carton and check it for damage and expiration date. **Do not** use if the expiration date has passed because it may not be safe to use (see **FIGURE A**). Return any remaining ACTPens in the box to the refrigerator. Do not use the ACTPen if it appears to be damaged or if you have accidentally dropped the ACTPen

Let ACTPen warm up and check liquid

- Let the ACTPen sit for 45 minutes to reach room temperature. If the ACTPen 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. **Do not** leave the ACTPen to warm up in direct sunlight. **Do not** remove the green cap while allowing your ACTPen to reach room temperature
- Hold your ACTPen with the green cap pointing down. Check the liquid in the clear window area. 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 ACTPen in a sharps container and get a new one
- Wash your hands well with soap and water

Please refer to the full ACTEMRA Instructions for Use for the complete FDA-approved step-by-step instructions on how to perform a subcutaneous injection.

Please see additional Important Side Effect Information on pages 9-10. For more Important Safety Information, please see full [Prescribing Information](#) and [Medication Guide](#), including **Serious Side Effects**.

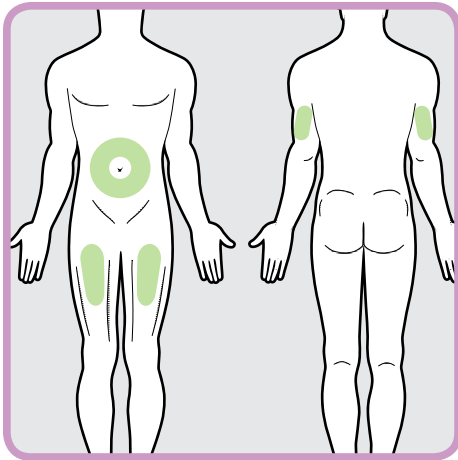


FIGURE B

2 Choose and prepare injection site

Choose an injection site

- The front of your thigh and your abdomen (except for the 2-inch area, which is roughly the width of 3 fingers, around your navel) are the recommended injection sites (see FIGURE B)
- The outer area of the upper arms may also be used only if the injection is given by a caregiver

Rotate injection site

- Choose a different injection site for each new injection at least 1 inch (which is roughly the length between the tip of your thumb and your knuckle) from the last site. **Do not** inject into moles, scars, bruises, or areas where the skin is tender, red, hard, or not intact

Prepare injection site

- Wipe the injection site with an alcohol pad. **Do not** touch the injection site again before self-injecting. **Do not** fan or blow on the clean area

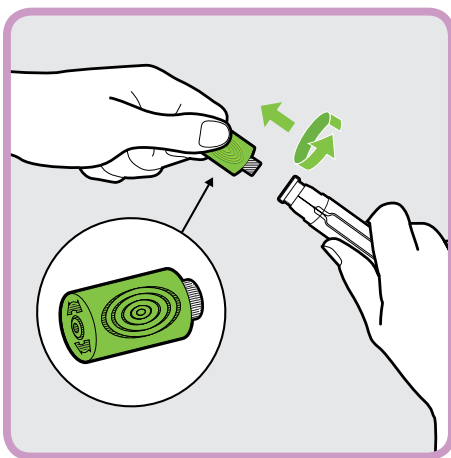


FIGURE C

3 Remove needle cap

- Twist and pull off the green cap (see FIGURE C)
 - The green cap contains a loose-fitting metal tube; this is normal
- **Do not touch the needle shield, which is located at the tip of the ACTPen below the Window area (see FIGURE A), to avoid accidental needle stick injury**
- Dispose of the green cap in a sharps container. Never reattach the green cap, as that may bend and damage the needle
- After you remove the green cap, the ACTPen is ready for use. If the ACTPen is not used within 3 minutes of the cap removal, the ACTPen should be disposed of in the sharps container and a new ACTPen should be used

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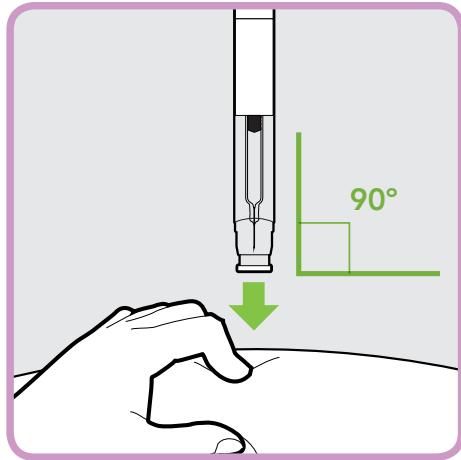


FIGURE D

4 Push ACTPen against skin to unlock device

- Hold the ACTPen comfortably in one hand so that you can see the window area of the ACTPen
- Gently pinch the injection site to provide a firm surface. Hold the pinched skin firmly to make sure that you inject under the skin (into fatty tissue) but not any deeper (into muscle) (see FIGURE D)
- Place the ACTPen at the injection site at a 90° angle (see FIGURE D)
 - **Do not** attempt to press the green activation button yet
- 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

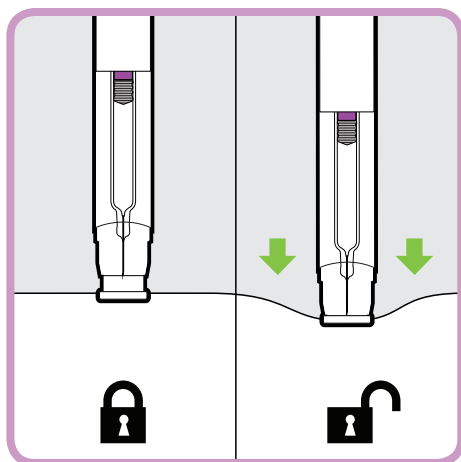


FIGURE E

- To unlock the green activation button, firmly push down the ACTPen until the needle shield is completely pushed in (see FIGURE E)
 - If the needle shield is not completely pushed in, the activation button will not work
 - Continue to pinch the skin while you keep the ACTPen in place

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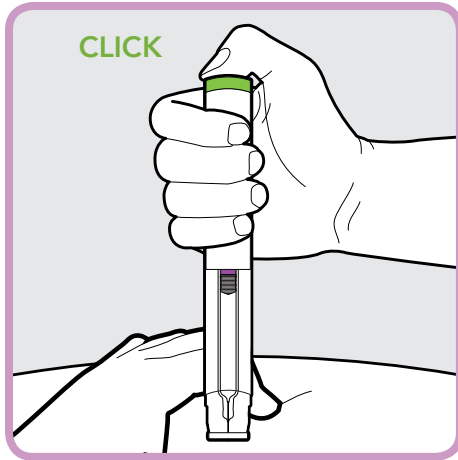


FIGURE F

5 Press green activation button and watch purple indicator

- Press the green activation button (see **FIGURE F**)
 - You will hear a “click” sound that indicates the start of the injection

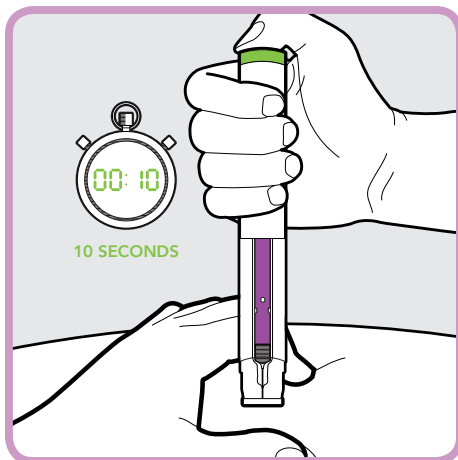


FIGURE G

- **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** (see **FIGURE G**)
 - You may hear a second “click” during the injection, but you should continue to hold the ACTPen firmly against your skin until the purple indicator stops moving

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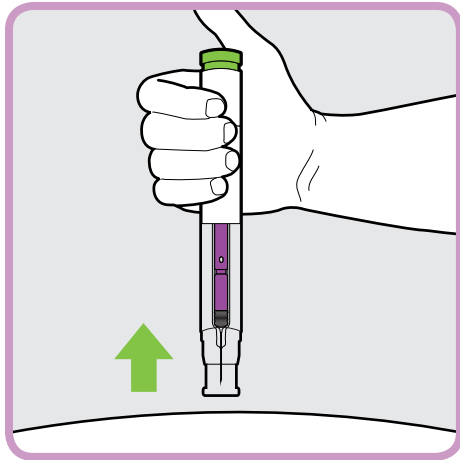


FIGURE H

6 Remove from skin

- Lift the ACTPen straight off your skin at a 90° angle and release the activation button
- The needle shield will extend and cover the needle (see FIGURE H)
 - If the window area is filled with the purple indicator, the entire dose has been delivered
- If the window area is not filled by the purple indicator:
 - The needle shield may not have locked. **Do not** touch the needle shield. Carefully place the ACTPen into a sharps container
 - You may not have received your full dose. **Do not** try to reuse the ACTPen. **Do not** repeat the injection with another ACTPen. Call your healthcare provider for help
- There may be a little bleeding at the injection site. **Do not** rub the injection site. If needed, you may cover the injection site with a small bandage



FIGURE I

7 Dispose of ACTPen

- **Do not** reuse the ACTPen and **do not** put the cap back on
- **If your injection was given by a caregiver, they must be careful when removing and disposing of the ACTPen to prevent accidental needle stick injury and passing infection**
- Dispose of the ACTPen in an FDA-cleared sharps disposal container or puncture-resistant container (see FIGURE I)
- 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

Please refer to the full ACTEMRA Instructions for Use for the complete FDA-approved step-by-step instructions on how to perform a subcutaneous injection.

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7 Dispose of ACTPen (continued)

- 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>
- **Keep the ACTPens and disposal containers out of the reach of children**
- Record the date, time, and part of your body where you performed your injection

For all questions, or to request your free ACTEMRA Travel Pack and sharps container, **call 1-800-ACTEMRA (1-800-228-3672).**

Please refer to the full ACTEMRA Instructions for Use for the complete FDA-approved step-by-step instructions on how to perform a subcutaneous injection.

Please see additional Important Side Effect Information on pages 9-10. For more Important Safety Information, please see full [Prescribing Information](#) and [Medication Guide](#), including **Serious Side Effects**.

IMPORTANT SIDE EFFECT INFORMATION

What does ACTEMRA treat?

ACTEMRA is a prescription medicine called an interleukin-6 (IL-6) receptor antagonist.

ACTEMRA is used to treat:

- Adults with moderately to severely active rheumatoid arthritis (RA) after at least one other medicine called a disease modifying antirheumatic drug (DMARD) has been used and did not work well
- Adults with giant cell arteritis (GCA)
- Patients with active polyarticular juvenile idiopathic arthritis (PJIA) 2 years of age and older
- Patients with active systemic juvenile idiopathic arthritis (SJIA) 2 years of age and older

It is not known if ACTEMRA is safe and effective in children with PJIA or SJIA under 2 years of age or in children with conditions other than PJIA or SJIA.

ACTEMRA can cause serious side effects

Serious Infections

ACTEMRA changes the way your immune system works. This can make you more likely to get infections or make any current infection worse. Some people have died from these infections. Your healthcare provider should test you for TB before starting and during treatment with ACTEMRA.

Before starting ACTEMRA, tell your healthcare provider if you have:

- an infection, think you may have an infection, are being treated for an infection, or get a lot of infections that return. Symptoms of an infection, with or without a fever, include sweating or chills; shortness of breath; warm, red or painful skin or sores on your body; feeling very tired; muscle aches; blood in phlegm; diarrhea or stomach pain; cough; weight loss; burning when you urinate or urinating more than normal
- any of the following conditions that may give you a higher chance of getting infections: diabetes, HIV, or a weak immune system
- tuberculosis (TB), or have been in close contact with someone with TB
- live or have lived, or have traveled to certain parts of the United States where there is an increased chance of getting fungal infections. These parts include the Ohio and Mississippi River valleys and the Southwest
- hepatitis B or have had hepatitis B

Who should not take ACTEMRA?

Do not take ACTEMRA if you are allergic to tocilizumab, or any of the ingredients in ACTEMRA.

Be sure to talk to your healthcare provider if you see any signs of these serious side effects:

Tears (perforation) of the Stomach or Intestines

If you have diverticulitis (inflammation in parts of the large intestine), talk to your healthcare provider before taking ACTEMRA. Some people taking ACTEMRA may develop a hole in the wall of their stomach or intestines (also known as a perforation). This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate.

Tell your healthcare provider right away if you see any of these side effects: fever, stomach-area pain that does not go away, or if you see a change in your bowel habits.

Changes in Blood Test Results

Your healthcare provider should do blood tests before you start receiving ACTEMRA. If you have rheumatoid arthritis (RA) or giant cell arteritis (GCA) your healthcare provider should do blood tests 4 to 8 weeks after you start receiving ACTEMRA and then every 3 months after that. If you have polyarticular juvenile idiopathic arthritis (PJIA) you will have blood tests done every 4 to 8 weeks during treatment. If you have systemic juvenile idiopathic arthritis (SJIA) you will have blood tests done every 2 to 4 weeks during treatment. These blood tests are to check for the following side effects of ACTEMRA:

- Low neutrophil count: neutrophils are white blood cells that help the body fight infection
- Low platelet count: platelets are blood cells that help with clotting, which stops bleeding
- Increase in liver function test levels
- Increase in blood cholesterol levels: your cholesterol levels should be checked 4 to 8 weeks after the start of your treatment, and then every 6 months after that

Please see additional Important Safety Information on page 10. For more Important Safety Information, please see full [Prescribing Information](#) and [Medication Guide](#), including **Serious Side Effects**.

 **ACTEMRA**[®]
tocilizumab

IMPORTANT SIDE EFFECT INFORMATION (continued)

You should not receive ACTEMRA if your neutrophil and platelet counts are too low or your liver function test levels are too high. These may cause your healthcare provider to stop your ACTEMRA treatment for a time or change your dose.

Cancer

ACTEMRA may increase your risk of certain cancers by changing the way your immune system works.

Hepatitis B Infection

If you have or are a carrier of the hepatitis B virus (a virus that affects the liver), the virus may become active while you use ACTEMRA. Your healthcare provider may do blood tests before you start treatment with ACTEMRA and while you are using ACTEMRA. Tell your healthcare provider if you have any signs of these symptoms:

- feel very tired
- skin or eyes look yellow
- little or no appetite
- vomiting
- clay-colored bowel movements
- fevers
- chills
- stomach discomfort
- muscle aches
- dark urine
- skin rash

Serious Allergic Reactions

Serious allergic reactions, including death, can happen with ACTEMRA. These reactions can happen with any infusion or injection of ACTEMRA, even if they did not occur with an earlier infusion or injection. Tell your healthcare provider before your next dose if you had hives, rash or flushing after your injection.

Contact 911 immediately, as well as your healthcare provider, if you experience any of these reactions:

- shortness of breath or trouble breathing
- swelling of the lips, tongue, or face
- chest pain
- feeling dizzy or faint
- moderate or severe abdominal pain or vomiting

Nervous System Problems

While rare, Multiple Sclerosis has been diagnosed in people who take ACTEMRA.

The most common side effects of ACTEMRA include:

- upper respiratory tract infections (common cold, sinus infections)
- headache
- increased blood pressure (hypertension)
- injection site reactions

ACTEMRA & Pregnancy

Tell your healthcare provider if you are planning to become pregnant, are pregnant, plan to breast-feed, or are breast-feeding. You and your healthcare provider should decide if you will take ACTEMRA or breast-feed. You should not do both. If you are pregnant and taking ACTEMRA, join the pregnancy registry. The purpose of this registry is to check the health of the pregnant mother and her baby. To learn more, call 1-877-311-8972 or talk to your healthcare provider to register.

Tell your healthcare provider if you have any side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Genentech at 1-888-835-2555.

Please see full [Prescribing Information](#) and the [Medication Guide](#), including **Serious Side Effects**, for more Important Safety Information.