A PATIENT’S GUIDE
TO TREATING GCA
WITH ACTEMRA

WHAT IS ACTEMRA?
ACTEMRA is a prescription medicine that targets the interleukin-6 (IL-6) signaling pathway. ACTEMRA is used to treat adults with giant cell arteritis (GCA).

IMPORTANT SIDE EFFECT INFORMATION
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 taking ACTEMRA have died from these infections.

Please see Important Side Effect Information on pages 16-21. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects.
WELCOME TO ACTEMRA

Now that you have been prescribed ACTEMRA subcutaneous (SC) injections, it is normal to have questions. In this brochure, we hope to provide a better understanding of what giant cell arteritis (GCA) is and how ACTEMRA may help.

Patient support resources
Have questions? Call the ACTEMRA Help Line at 1-800-228-3672 to speak with one of our specialists. You may qualify for financial assistance. For more information on help paying for your treatment, please see pages 22-24.

ACTEMRA can cause serious side effects
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 serious infections while taking ACTEMRA, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections. Your healthcare provider should test you for TB before starting ACTEMRA.

Please see Important Side Effect Information on pages 16-21. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects.
What is GCA?

Giant cell arteritis, or GCA, causes inflammation in the medium and large blood vessels. These blood vessels are known as arteries. GCA most often causes problems in the arteries found in your head, specifically the temples. The aorta (the biggest artery leaving the heart) can also be affected, along with its branch arteries.

GCA typically occurs in people over 50, and most commonly in people between 70 and 80 years old. Women are 2 to 3 times more likely than men to develop GCA.

Explaining your disease to others may come as a challenge. Here’s one way you could explain GCA to friends and family:

“Some of my blood vessels are inflamed. It can cause headaches and jaw pain, and may affect my vision.”

UNDERSTANDING GCA

What are common symptoms of GCA?

- New-onset headaches
- Aches, pains, and stiffness in the shoulders, neck, or hips
- Scalp tenderness
- Jaw pain
- Vision problems
- Generally feeling unwell
- Weight loss
- Fever
- Weight loss

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There are a number of factors that help your healthcare provider determine if you have GCA. Symptoms (such as the ones on page 5) may offer the first sign. There are other important ways to help diagnose GCA. These include:

- Lab testing
- Imaging tests to detect inflammation in the arteries
- A temporal artery biopsy (TAB) performed by a surgeon, in which a sample of the blood vessel is removed and tested for inflammation

GCA should be treated as soon as possible following diagnosis. Serious issues may occur if GCA is left untreated, including blindness, stroke, and swelling of the arteries.

You’ve taken an important step by talking with your healthcare provider about GCA. It’s important that you continue to have these conversations throughout treatment.

Why is it important to be treated for GCA quickly?

GCA should be treated as soon as possible following diagnosis. Serious issues may occur if GCA is left untreated, including blindness, stroke, and swelling of the arteries.

Maintaining a healthy lifestyle is important—especially if you have GCA. Here are some tips to discuss with your healthcare provider*:

- Eat a healthy diet
  - Eat fresh fruits and vegetables, whole grains, lean meat, and fish
  - Take calcium and vitamin D to help prevent thinning bones

- Exercise, if your healthcare provider says you can
  - Speak with your healthcare provider to plan an exercise routine that’s right for you

- Get regular checkups

- Discuss the risks of smoking and drinking alcohol with your healthcare provider

*Tips on living with GCA provided by the Mayo Clinic.
Steroid treatment

Fortunately, there are options to treat GCA. Treatment usually involves high doses of initial steroids to control the inflammation. Once GCA is under control, the steroid dose can slowly be tapered off. While steroids have been proven in immediately treating the disease, long-term use of steroids may result in serious side effects.

As of May 2017, you have another option: ACTEMRA—the first and only FDA-approved biologic treatment for GCA.

What is a biologic treatment?

A biologic is a type of medication that is developed in living systems, and made from proteins that are similar to proteins that occur naturally. These treatments can be used to target certain parts of your immune system, and to fight inflammation in certain diseases such as GCA.

Important Side Effect Information | Hepatitis B Infection

If you have hepatitis B, a virus that affects the liver, or are a carrier of the virus, ACTEMRA can cause the virus to become active. Your healthcare provider should test you for hepatitis B before starting treatment. Tell your healthcare provider right away if you see any signs of these symptoms: feeling very tired, vomiting, chills, dark urine, skin or eyes look yellow, clay-colored bowel movements, stomach discomfort, skin rash, little or no appetite, fevers, or muscle aches.
With ACTEMRA, you have an option for treating GCA that may reduce your overall exposure to steroids. ACTEMRA has been used to treat over half a million patients with other conditions since 2010. As of May 2017, it’s also a treatment option for patients with GCA.

ACTEMRA is a prescription medicine that targets the IL-6 signaling pathway and is used to treat adults with GCA.

ACTEMRA helps block the action of interleukin-6 (IL-6), a protein in your body. Research has shown that patients with GCA may have a higher amount of IL-6 in their bodies.

Important Side Effect Information | Stomach tears
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.
ACTEMRA may help achieve remission when taken with steroids that are tapered off over time

RESULTS OF THE ACTEMRA CLINICAL TRIAL IN GCA

The GCA clinical trial included patients receiving two types of treatment:

1. ACTEMRA plus steroids that were tapered off by 6 months
   • Some patients took ACTEMRA once a week; some took ACTEMRA every 2 weeks

2. Steroids alone
   • Some patients tapered off steroids at 6 months, some at 1 year

The percentage of patients who achieved sustained remission when treated with ACTEMRA weekly plus an initial dose of steroids was 4 times larger when compared with patients taking steroids alone, tapering off at 6 months.

251 patients were included in this clinical trial.

- Results for all patient groups: 56% (ACTEMRA weekly) and 53.1% (ACTEMRA every 2 weeks) vs 14% (6-month steroid taper group) and 17.6% (1-year steroid taper group)

ACTEMRA may help achieve remission when taken with steroids that are tapered off over time

ACTEMRA may increase your risk of certain cancers by changing the way your immune system works.
If you’ve never had injection therapy before, you may be wondering what to expect. Here are a few things that will happen before, during, and after your treatment.

Blood tests: At the start of your ACTEMRA treatment, and 4 to 8 weeks after your first injection, your healthcare provider will take blood tests. He or she will repeat the tests every 3 months to check for changes in your liver function tests, neutrophil count, and platelet count.

Your healthcare provider should also do blood tests to check your cholesterol levels 4 to 8 weeks after your first ACTEMRA SC injection, and then every 24 weeks.

Getting to know your treatment: Before you start on ACTEMRA SC injections, it’s important to know all the facts. So make sure you review the ACTEMRA Medication Guide, available at ACTEMRA.com. Especially take note of the “What is the most important information I should know about ACTEMRA?” and “Before you receive ACTEMRA, tell your healthcare provider about all of your medical conditions” sections.

1. Your first injection: Your healthcare provider or nurse can help to train you or your caregiver in his or her office on how to properly inject ACTEMRA. During this training session, you or your caregiver should perform the first injection. You should not attempt to inject yourself before receiving this in-office training. Only patients or caregivers who have been properly trained should use the ACTEMRA prefilled syringe.

2. Monitoring for side effects at home: ACTEMRA may lead to serious allergic reactions, including death. So it’s important to pay close attention to how you’re feeling during and after an injection. Allergic reactions may happen during and after any injection, even if they have not happened before. 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

Learn more about what to expect at ACTEMRA.com/GCA

Please see Important Side Effect Information on pages 16-21. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects.
After reading about ACTEMRA, please talk to your healthcare provider if you have any questions.

**ACTEMRA is:**
- Available by medical prescription only
- For adults with giant cell arteritis (GCA)

**ACTEMRA can cause serious side effects**

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.

Before taking 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. Infection signs, with or without a fever, include:
  - Sweating or chills
  - Shortness of breath
  - Warm, red or painful skin or sores on your body
  - Feel very tired
  - Muscle aches
  - Blood in phlegm
  - Diarrhea or stomach pain
  - Cough
  - Weight loss
  - Burning when you urinate or urinating more often than normal

**IMPORTANT SIDE EFFECT INFORMATION**

- Any of the following conditions that may give you a higher chance of getting infections. These include: diabetes, HIV, or a weak immune system
- Tuberculosis (TB) or have been in close contact with someone who has TB. Your healthcare provider should test you for TB before starting ACTEMRA and during treatment with ACTEMRA
- Lived in or currently live in parts of the United States known for fungal infections. These parts include the Ohio and Mississippi River Valleys and the Southwest
- Hepatitis B or have had hepatitis B

Be sure to contact your healthcare provider or nurse if you see any signs of these side effects.

**Stomach tears**

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.

Please see full Prescribing Information and Medication Guide, including Serious Side Effects, for more Important Safety Information.
Tell your healthcare provider right away if you see any of these side effects:

- Fever
- Stomach-area pain that does not go away
- Change in your bowel habits

Before starting ACTEMRA, 4 to 8 weeks after starting treatment, and then every 3 months, your healthcare provider will regularly do blood tests to check for the following side effects:

**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**

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. Your cholesterol levels should be checked 4 to 8 weeks after the start of your treatment, and then every 6 months after that.

**IMPORTANT SIDE EFFECT INFORMATION (CONT’D)**

**Increased risk of cancer**

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

**Hepatitis B infection**

If you have hepatitis B, a virus that affects the liver, or are a carrier of the virus, ACTEMRA can cause the virus to become active. Your healthcare provider should test you for hepatitis B before starting treatment. Tell your healthcare provider right away if you see any signs of these symptoms:

- Feeling very tired
- Vomiting
- Chills

Please see full Prescribing Information and Medication Guide, including Serious Side Effects, for more Important Safety Information.
IMPORTANT SIDE EFFECT INFORMATION (CONT’D)

Serious allergic reactions
Serious allergic reactions, including death, can happen with ACTEMRA infusions or injections, even if they did not occur with an earlier infusion or injection. If you had hives, a rash, or experienced flushing after injecting, you should tell your healthcare provider or nurse before your next injection.

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

• Shortness of breath or trouble breathing
• Swelling of 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 some people taking ACTEMRA.

Most common side effects
Tell your healthcare provider if you have these or any other side effect that bothers you or does not go away:

• Upper respiratory tract infections (like common cold and sinus infections)
• Increased blood pressure (also called hypertension)
• Headache
• 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.

Reporting side effects
Tell your healthcare provider right away if you are experiencing any side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. You may also call Genentech at 1-888-835-2555.

Please see full Prescribing Information and Medication Guide, including Serious Side Effects, for more Important Safety Information.
ACTEMRA offers a variety of assistance programs that patients may be eligible for.

**TYPE OF HEALTH INSURANCE COVERAGE**

**Commercial Insurance**
- Patients eligible for the ACTEMRA Co-pay Card Program pay $5 per drug co-pay. The Co-pay Card may be used to cover co-pays, co-insurance, deductibles, or other out-of-pocket costs for ACTEMRA only. Terms and conditions apply.
  > For more information, go to page 23

**Government Insurance (Medicare and Medicaid)**
- Patients with Medicare Part D and limited incomes may be eligible for co-pay support through the government Low Income Subsidy (LIS) Program. Patients eligible for the full subsidy pay $8.25 per drug co-pay.
- Patients who don’t qualify for the LIS Program and who can’t afford their co-payments may be eligible for free drug through the Genentech® Access to Care Foundation (GATCF).
  > For more information, go to page 24

**Uninsured/Underinsured**
- Uninsured patients or those rendered uninsured by payer denial or the underinsured may be eligible for free drug through the Genentech® Access to Care Foundation (GATCF).
  > For more information, go to page 24

To learn more about how we can help, contact us. Call 1-800-ACTEMRA (1-800-228-3672)

**What should I know?**
- Eligible commercially insured patients pay $5 per drug co-pay, which can be applied to deductibles, co-pays, co-insurance, or other out-of-pocket costs for ACTEMRA.
- There are no income limits.
- The Co-pay Card covers your enrollment for 12 months at a time. You must reapply at the end of 12 months.
- The Co-pay Card can be used if you’re just starting ACTEMRA or if you’re already on ACTEMRA.

**How does it work?**
- For example, Julie is charged a $100 co-pay for her ACTEMRA. She pays $5 herself, and uses her Co-pay Card to cover the rest. She can use her card to cover up to $15,000 for ACTEMRA in co-pays during her enrollment year.

**Why may you be eligible for the Co-pay Card?**
- Your physician recommends ACTEMRA for an FDA-approved use such as Giant Cell Arteritis (GCA), and:
  > You have a commercial (private or nongovernmental) health plan. This includes plans available through state and federal exchanges
  > You are not receiving support from the Genentech® Access to Care Foundation (GATCF) or any other charitable organization
  > You do not use a federal or state-funded health care program. This includes, but is not limited to, Medicare; Medicaid; VA, DoD or TRICARE
  > You are 18 years or older and live and are treated in the United States or Puerto Rico and do not reside in any state where the program is prohibited by law

**What should I know?**
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To learn more about how we can help, contact us. Call 1-800-ACTEMRA (1-800-228-3672)
Some patients may be eligible for co-pay support through the government Low Income Subsidy (LIS) Program. These patients include:
• Medicare Part D patients
• Patients with limited incomes
Patients eligible for the full subsidy will pay $8.25 per drug co-pay.

Some patients may be eligible for free drug through the Genentech® Access to Care Foundation (GATCF). These patients include:
• Medicare patients who don’t qualify for the LIS Program and who can’t afford their co-payments
• Uninsured patients

Help for Medicare, Medicaid, and underinsured patients

Getting your ACTEMRA prescription

Call your specialty/mail-order pharmacy. If they are a participating pharmacy, provide the Rx BIN number and Member ID from your card. If they are not a participating pharmacy, call 1-866-681-3261 for assistance.

Contact Genentech Rheumatology Access Solutions® to learn more. We are available at 1-866-681-3261 from 6 AM-5 PM PT, Monday through Friday, or 24 hours a day at www.Genentech-Access.com/ACTEMRA.

Please see Important Side Effect Information on pages 16-21. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects.
By using the ACTEMRA Co-pay Card Program, the patient acknowledges and confirms that at the time of usage, (s)he is currently eligible and meets the criteria set forth in the terms and conditions described. This Co-pay Card is valid ONLY for patients with commercial (private or nongovernmental) insurance. Patients using Medicare, Medicaid or any other government funded program to pay for their medications are not eligible. Patients who start utilizing their Government coverage during their enrollment period will no longer be eligible for the program. This Co-pay Card program is not health insurance or a benefit plan. Distribution or use of the Co-pay Card does not obligate use or continuing use of any specific product or provider. Patient or guardian is responsible for reporting the receipt of all Co-pay Card program benefits or reimbursement received, to any insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using the Co-pay Card program, as may be required.

The Co-pay Card is not valid for medications the patient receives for free or that are eligible to be reimbursed by private insurance plans or other healthcare or pharmaceutical assistance programs (such as: GATCF or any other charitable organization) that reimburse the patient in part or for the entire cost of his/her medication. Patient, guardian, pharmacist, prescriber and any other person using the Co-pay Card agree not to seek reimbursement for all or any part of the benefit received by the recipient through the offer. The Co-pay Card will be accepted by participating pharmacies, physician offices or hospitals. To qualify for the benefits of this Co-pay Card program, the patient may be required to pay out-of-pocket expenses for each treatment. Once enrolled, this Co-pay Card program will not honor claims with date of service or medication dispensing that precede program enrollment by more than 120 days. This Co-pay Card is only available with a valid prescription and cannot be combined with any other rebates, free trial, or similar offer for the specified prescription. Use of this Co-pay Card must be consistent with all relevant health insurance requirements and payer agreements. Participating patients, physicians, pharmacy offices and hospitals are obligated to inform third-party payers about the use of this Co-pay Card as provided for under the applicable insurance or as otherwise required by contract or law. The Co-pay Card may be sold, traded or offered for sale, purchase or trade. The Co-pay Card is limited to 1 per person during this offering period and is not transferable. The program expires within 12 months from enrollment. This program is not valid where prohibited by law. For Massachusetts residents, the Co-pay Card is not valid for any prescription drug that has an AB-rated generic equivalent as determined by the United States Food and Drug Administration. For Massachusetts residents, this program shall expire on or before July 1, 2019.

The patient or their guardian must be 18 years or older to receive Co-pay Card program assistance. This Co-pay Card program is (1) void if the card is reproduced; (2) void where prohibited by law; (3) only valid in the United States and Puerto Rico; and (4) only valid for Genentech products. Healthcare providers may not advertise or otherwise use the program as a means of promoting their services or Genentech’s products to patients. Genentech, Inc. reserves the right to rescind, revoke, or amend the program without notice at any time.

Terms and conditions

Living with GCA? How ACTEMRA may help

The ACT Fast Program ensures quick access to therapy

For eligible commercial and government insured patients waiting longer than 5 days for a coverage decision, the ACT Fast Program provides ACTEMRA SC at no charge for up to 6 months or until coverage is established, whichever comes first. For more information, call 1-800-ACTEMRA.
A PATIENT’S GUIDE TO USING THE PREFILLED SYRINGE

Please see full Instructions for Use before using the prefilled syringe.

WHAT IS ACTEMRA?
ACTEMRA is a prescription medicine that targets the interleukin-6 (IL-6) signaling pathway. ACTEMRA is used to treat adults with giant cell arteritis (GCA).

IMPORTANT SIDE EFFECT INFORMATION
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 taking ACTEMRA have died from these infections.

Please see Important Side Effect Information on pages 25-27. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects, as well as full Instructions for Use.
LEARNING TO SELF-INJECT WITH THE ACTEMRA PREFILLED SYRINGE

By choosing ACTEMRA subcutaneous (SC) injections, you and your healthcare provider have taken an important step in treating your giant cell arteritis (GCA). This easy-to-follow injection brochure will help you or your caregiver feel comfortable and confident using the ACTEMRA prefilled syringe. If you still have questions, a team of experts are here to help. Simply call 1-800-ACTEMRA (1-800-228-3672), Monday-Friday from 9 AM to 9 PM ET, for additional support.

INSIDE YOU’LL FIND INFORMATION ABOUT:

- Getting to know the ACTEMRA prefilled syringe
- Preparing for your injection
- Steps to self-injection
- Important Side Effect Information

Please see Important Side Effect Information on pages 25-27. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects, as well as full Instructions for Use.
UNDERSTANDING THE ACTEMRA PREFILLED SYRINGE

**Needle Cap** | Do not remove the needle cap while allowing your ACTEMRA prefilled syringe to reach room temperature. Hold the ACTEMRA prefilled syringe with the covered needle pointed down.

**Liquid** | Check the liquid. It should be clear and colorless to pale yellow. Do not inject if the liquid is cloudy, discolored, or has lumps or particles. Do not speed up the warming in any way, such as with a microwave or warm water.

**Expiration Date** | Always check date. Do not use it if the expiration date has passed.

**Trigger Fingers** | Do not touch, as this may release the needle shield early.

**Plunger** | Do not hold or pull back on the plunger. You must press the plunger all the way down to get the full dose of medication.

**Needle** | Do not touch the needle or let it touch any surface. The syringe should be disposed of if not used within 5 minutes of needle cap removal.

UNDERSTANDING YOUR DOSE

The recommended dose of ACTEMRA subcutaneous (SC) injection for GCA is:

- 1 prefilled syringe (162 mg) once a week, every other week, or as prescribed by your healthcare provider
- ACTEMRA can be used alone after steroids have been stopped
- ACTEMRA SC injection should never be given intravenously (into a vein)

Throughout treatment, your healthcare provider will closely monitor your lab results to see how you’re responding to ACTEMRA and check for possible side effects.

Please see Important Side Effect Information on pages 25-27. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects, as well as full Instructions for Use.
IMPORTANT INFORMATION ABOUT THE 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 the ACTEMRA prefilled syringe for the first time, make sure your healthcare provider shows you how to use it.
- Do not remove the needle cap until you’re ready to inject ACTEMRA.
- Do not try to take apart the syringe at any time.
- Do not reuse the same syringe.

If you feel your ACTEMRA prefilled syringe is damaged or have any other concerns, please call the ACTEMRA Help Line at 1-800-ACTEMRA (1-800-228-3672), Monday-Friday from 9 AM to 9 PM ET.

THE ACTEMRA PREFILLED SYRINGE

Before use
- Trigger Fingers. Do not touch, as this may release the needle shield early.

After use
- Needle Shield (extended and locked)

Please see Important Side Effect Information on pages 25-27. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects, as well as full Instructions for Use.
Preparing for your injection

- A well-lit, clean, flat surface such as a table
- A new ACTEMRA prefilled syringe
- Alcohol pads (available at your local pharmacy)
- A puncture-resistant container or sharps container
- Cotton ball or gauze (available at your local pharmacy)

If I have any questions about injecting ACTEMRA, it’s comforting to know I have the ACTEMRA Help Line.

ACTEMRA Help Line 1-800-228-3672
Find a comfortable space with a clean, flat 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 one single-use ACTEMRA prefilled syringe from the box and let it sit for 30 minutes 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 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.

Expiration date on box
Expiration date on syringe

FIGURE A

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-46°F (2°C-8°C).

Do not freeze

Hold your ACTEMRA prefilled syringe with the covered needle pointing down (see FIGURE B).

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.
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 C).

- 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 C).

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.

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 (see FIGURE D).

- Do not touch the injection site again before giving the injection.

- Do not fan or blow on the clean area.

Please see Important Side Effect Information on pages 25-27. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects, as well as full Instructions for Use.
Step 3: Inject ACTEMRA

- Hold the ACTEMRA prefilled syringe with one 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.
- Dispose of the needle cap in a sharps container or a puncture-resistant container (see FIGURE F).
- 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 one hand between the thumb and index finger (see FIGURE G).

Please see Important Side Effect Information on pages 25-27. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects, as well as full Instructions for Use.
Step 3: Inject ACTEMRA (cont’d)

- 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 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° and 90° (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.
- Keep the syringe in position, and let go of the pinched skin

Slowly inject all of the medicine by gently pushing the plunger all the way down (see FIGURE I). 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 sharps container or puncture-resistant container to avoid injury with the needle. Do not put the needle cap back on the needle

Keep in mind that the ACTEMRA solution in the syringe is thicker than water. It may take some pressure to push the plunger all the way down.

Please see Important Side Effect Information on pages 25-27. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects, as well as full Instructions for Use.
Step 3: Inject ACTEMRA (cont’d)

- 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 J).
- After the needle is removed completely from the skin, release the plunger, allowing the needle shield to protect the needle (see FIGURE K).

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.

Please see Important Side Effect Information on pages 25-27. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects, as well as full Instructions for Use.
The ACTEMRA prefilled syringe should not be reused
Put the used syringe in your sharps container or puncture-resistant container (see FIGURE L)
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 needle and disposing of the syringe to prevent accidental needle stick injury and avoid passing infection.

How do I dispose of used syringes?
• Put your used needles and syringes, including ACTEMRA, in an FDA-cleared sharps disposal container or a puncture-resistant container right away after use. Do not dispose of loose needles and syringes in your household trash
• When your sharps disposal container or puncture-resistant container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container or puncture-resistant container. There may be state or local laws about how you should dispose of used needles and syringes. For more information about safe sharps container and puncture-resistant container disposal, and for specific information about sharps container disposal and puncture-resistant container disposal in the state you live in, go to the FDA’s website at www.fda.gov/safesharpsdisposal
• Do not dispose of your used sharps disposal container or puncture-resistant container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container or puncture-resistant container
• Keep ACTEMRA prefilled syringes and the sharps disposal container or puncture-resistant container out of the reach of children
• Record your injection: Write down the date, time, and specific part of your body where you injected yourself. It may also be helpful to write down any questions or concerns about the injection so you can ask your healthcare provider

Please see Important Side Effect Information on pages 25-27. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects, as well as full Instructions for Use.
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. Seek medical attention right away if you have any of the following signs of a serious allergic reaction:

- 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

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.

Call your healthcare provider and seek medical attention without delay if you think you might be developing an infection.

If you have any concerns or questions about your syringe, contact your healthcare provider or pharmacist for assistance.

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

Please see Important Side Effect Information on pages 25-27. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects, as well as full Instructions for Use.
PATIENT SUPPORT

There are several resources offered to patients treating their GCA with ACTEMRA

Have questions? Call the ACTEMRA Help Line at 1-800-228-3672 to speak live with one of our specialists.

You may qualify for financial assistance. For more information on help paying for your treatment, please see pages 22-27 in the accompanying brochure.

IMPORTANT SIDE EFFECT INFORMATION

After reading about ACTEMRA, please talk to your healthcare provider if you have any questions.

ACTEMRA is:

- Available by medical prescription only
- For adults with giant cell arteritis (GCA)

ACTEMRA can cause serious side effects

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 serious infections while taking ACTEMRA, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections. Your healthcare provider should test you for TB before starting ACTEMRA.

Please see full Prescribing Information and Medication Guide, including Serious Side Effects, for more Important Safety Information, as well as full Instructions for Use.
ACTEMRA can cause other serious side effects
These include:

- Stomach tears
- Changes in blood test results, including low neutrophil and platelet counts, and increases in certain liver function test levels and blood cholesterol levels
- An increased risk of certain cancers by changing the way your immune system works

Do not take ACTEMRA if you:

- Are allergic to ACTEMRA, or any of the ingredients in ACTEMRA
- Have hepatitis B infection
- Have serious allergic reactions, including death. These may happen with ACTEMRA infusions or injections, even if they did not occur with an earlier infusion or injection. If you had hives, a rash, or experienced flushing after injecting, you should tell your healthcare provider or nurse before your next injection
- Have nervous system problems

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Most common side effects
Tell your healthcare provider if you have these or any other side effect that bothers you or does not go away:

- Upper respiratory tract infections (like common cold and sinus infections)
- Increased blood pressure (also called hypertension)
- Headache
- 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. To learn more, call 1-877-311-8972 or talk to your healthcare provider to register.

Reporting side effects
Tell your healthcare provider right away if you are experiencing any side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. You may also call Genentech at 1-888-835-2555.

Please see full Prescribing Information and Medication Guide, including Serious Side Effects, for more Important Safety Information, as well as full Instructions for Use.
Visit ACTEMRA.com/GCA or call 1-800-ACTEMRA (1-800-228-3672) for more information

Please see Important Side Effect Information on pages 25-27. For more Important Safety Information, please see full Prescribing Information and Medication Guide, including Serious Side Effects, as well as full Instructions for Use.

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