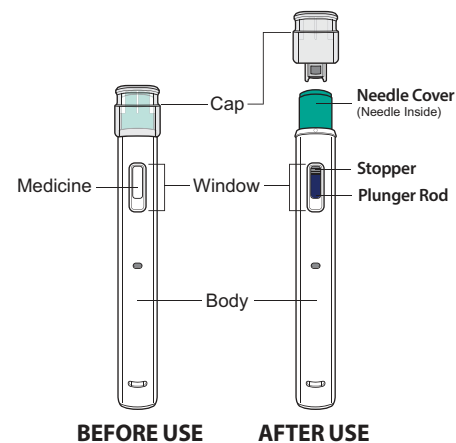


How do I inject the Prefilled Auto-injector?

Adalimumab-aaty is offered in an easy-to-use Prefilled Auto-injector device. The following steps will guide you to a safe and easy administration of Adalimumab-aaty.

Adalimumab-aaty

Auto-injector (AI)



Important information

- Use the Prefilled Auto-injector **only if** your healthcare provider has trained you in preparing and giving the injection.
- Ask your healthcare provider how often you will need to give the injection.
- **Do not** shake the Prefilled Auto-injector at any time.
- **Do not** remove the Cap until you are ready to inject.
- **Do not** share the Prefilled Auto-injector with anyone.
- Only use each Prefilled Auto-injector for one injection.

Prepare for the injection

GATHER THE SUPPLIES

- Prepare a clean, flat, and well-lit surface such as a table.
- Remove the Prefilled Auto-injector from the carton stored in your refrigerator.

Items needed for injection:

Auto-injector, alcohol swab, cotton ball or gauze*, adhesive bandage*, sharps disposal container*

* Items not included in the carton.

INSPECT THE AUTO-INJECTOR AND THE MEDICINE

- Check the correct Medicine and dosage.
- Check the expiration date on the label of the Auto-injector.
- Look through the Window and make sure the liquid is clear, colorless to pale brown and free of particles.
- * **Do not** use the Auto-injector if it has been cracked or is visibly damaged.
- * **Do not** use the Auto-injector if the liquid is discolored, cloudy, or contains particles.
- * It is normal for air bubbles to be seen in the liquid.

WAIT 15 TO 30 MINUTES

- Leave the Auto-injector at room temperature (68 °F to 77 °F) for 15 to 30 minutes to let it warm up.
- * **Do not** warm the Auto-injector using heat sources.

CHOOSE AN INJECTION SITE

- Select an injection site.
- Possible injection sites:

- The front of your thighs.
- Your abdomen except for the 2 in (5 cm) around the belly button (navel).

* **Do not** inject into skin that is within 2 in (5 cm) of your belly button (navel) or is tender, damaged, bruised, or scarred.

- Rotate the injection site each time you give an injection.
- Each new injection site should be at least 1.2 in (3 cm) away from the previous site.

WASH YOUR HANDS AND CLEAN THE INJECTION SITE

- Wash your hands with soap and water and dry them fully.
- Clean the injection site with an alcohol swab.
- Let the skin dry before injecting.

* **Do not** blow on or touch the injection site.

Give the injection

Step 1

REMOVE THE CAP

- Hold the Auto-injector by the injector body with the Cap on top.
- Pull the Cap straight off.
- * **Do not** remove the Cap until you are ready to inject.
- * **Do not** touch the Needle or Needle Cover.
- * **Do not** recap the Auto-injector. Dispose of the Cap immediately into the sharps disposal container.

Step 2

PLACE THE AUTO-INJECTOR

- Hold the Auto-injector so that you can see the Window.
- Without pinching or stretching the skin, place the Auto-injector over the injection site at a 90-degree angle.

GIVE THE INJECTION

- Press the Auto-injector **firmly** against the skin.
- When the injection starts you will hear the 1st loud “click” and the Blue Plunger Rod will begin to fill the Window.
- Keep holding the Auto-injector and listen for the 2nd loud “click”.
- After the 2nd loud “click”, continue to hold the Auto-injector and **count slowly to 5**.
- * **Do not** change the position of the Auto-injector after the injection has started.

REMOVE THE AUTO-INJECTOR

- Make sure that the Blue Plunger Rod with the gray top has filled the Window completely.
- Remove the Auto-injector from your skin.
- Gently press a cotton ball or gauze over the injection site.
- * **Do not** reuse the Auto-injector.
- * **Do not** rub the injection site.
- * If the Window has not turned completely blue, this means you have not received a full dose. Call your healthcare provider immediately.

After the injection

DISPOSE OF THE AUTO-INJECTOR

- Put the used Auto-injector in a FDA-cleared sharps disposal container right away after use.
- * **Do not** throw away (dispose of) the Auto-injector in your household trash. If you do not have an FDA-cleared sharps disposal container, you may use a household container that is: made of a heavy-duty plastic, can be closed with a tight-fitting, puncture-resistant lid without sharps being able to come out, upright and stable during use, leak-resistant, and properly labeled to warn of hazardous waste inside the container.

IMPORTANT SAFETY INFORMATION ABOUT ADALIMUMAB-AATY

What is the most important information I should know about Adalimumab-aaty?

You should discuss treatment characteristics of Adalimumab-aaty with your doctor, including potential benefits and risks. Adalimumab-aaty is a TNF blocker medicine that can lower the ability of your immune system to fight infections. Notify your doctor if you have any kind of infection before you start taking Adalimumab-aaty.

How do I inject the Prefilled Syringe?

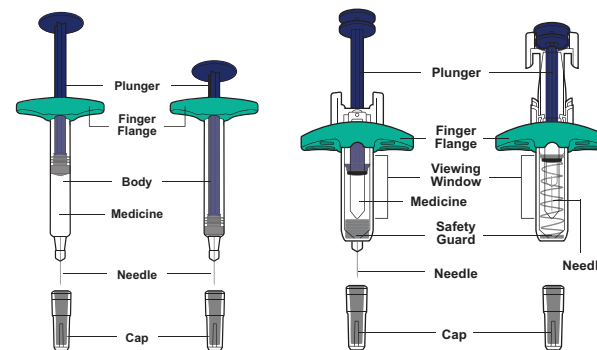
Adalimumab-aaty is offered in two easy-to-use Syringe types. The following steps will guide you to a safe and easy administration of Adalimumab-aaty.

Adalimumab-aaty

Prefilled Syringe

Prefilled Syringe

With Safety Guard



Important information

- Use the Prefilled Syringe **only** if your healthcare provider has trained you in preparing and giving the injection.
- Ask your healthcare provider how often you will need to give the injection.
- **Do not** shake the Syringe at any time.
- **Do not** remove the Cap until you are ready to inject.
- **Do not** share the Syringe with anyone.
- Only use each Syringe for one injection.

Prepare for the injection

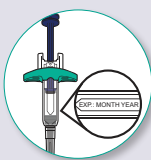
GATHER THE SUPPLIES



- Prepare a clean, flat, and well-lit surface such as a table.
- Remove the Syringe from the carton stored in your refrigerator.
- **Items needed for injection:**
Syringe, alcohol swab, cotton ball or gauze*, adhesive bandage*, sharps disposal container*

* Items not included in the carton.

INSPECT THE SYRINGE AND THE MEDICINE



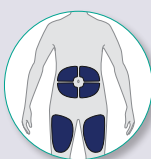
- Check the correct Medicine and dosage.
- Check the expiration date on the label of the Syringe.
- Look through the Window and make sure the liquid is clear, colorless to pale brown and free of particles.
- * **Do not** use the Syringe if it has been cracked or is visibly damaged.
- * **Do not** use the Syringe if the liquid is discolored, cloudy, or contains particles.
- * It is normal for air bubbles to be seen in the liquid.

WAIT 15 TO 30 MINUTES



- Leave the Syringe at room temperature 68 °F to 77 °F (20 °C to 25 °C) for 15 to 30 minutes to allow it to warm up.
- * **Do not** warm the Syringe using heat sources.

CHOOSE AN INJECTION SITE



- Select an injection site.
- Possible injection sites:
- The front of your thighs.
- Your abdomen except for the 2 in (5 cm) around the belly button (navel).
- * **Do not** inject into skin that is within 2 in (5 cm) of your belly button (navel) or is tender, damaged, bruised, or scarred.
- Rotate the injection site each time you give an injection.
- Each new injection site should be at least 1.2 in (3 cm) away from the previous site.

■ = Self-injection and Caregiver

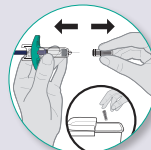
WASH YOUR HANDS AND CLEAN THE INJECTION SITE



- Wash your hands with soap and water and dry them fully.
- Clean the injection site with an alcohol swab.
- Let the skin dry before injecting.
- * **Do not** blow on or touch the injection site.

Give the injection

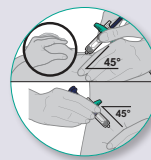
Step 1



REMOVE THE CAP

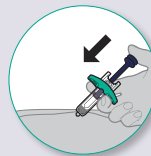
- Hold the prefilled Syringe by the body in one hand.
- Pull the Cap straight off.
- * **Do not** remove the Cap until you are ready to inject.
- * **Do not** touch the needle.
- * **Dispose** of the Cap immediately into the sharps disposal container.

Step 2



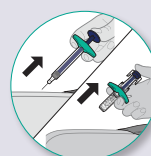
INSERT THE SYRINGE

- Gently pinch a fold of skin at the injection site.
- While holding the Syringe by its body, insert the Needle completely into the fold of the skin at a 45-degree angle with a quick and "dart-like" motion.



GIVE THE INJECTION

- After the Needle is inserted, let go of the pinched skin.
- Push the Plunger slowly all the way down until the Syringe is empty.
- * **Do not** change the position of the Syringe after the injection has started.

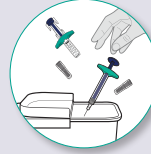


REMOVE THE SYRINGE

- If using the Prefilled Syringe:**
 - Remove the Syringe from your skin at the same angle it was inserted.
- If using the Prefilled Syringe With Safety Guard:**
 - Slowly lift your thumb from the Plunger until the Needle is completely covered by the Automatic Safety Guard.
 - Gently press a cotton ball or gauze over the injection site and apply an adhesive bandage if necessary.
 - * **Do not** rub the injection site.

After the injection

DISPOSE OF THE SYRINGE



- Put the used Prefilled Syringe in a FDA-cleared sharps disposal container right away after use.
- * **Do not** throw away (dispose of) the Syringe in your household trash. If you do not have an FDA-cleared sharps disposal container, you may use a household container that is: made of a heavy-duty plastic, can be closed with a tight-fitting, puncture-resistant lid without sharps being able to come out, upright and stable during use, leak-resistant, and properly labeled to warn of hazardous waste inside the container.

IMPORTANT SAFETY INFORMATION continued

- **Serious infections have happened in people taking adalimumab products, including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some of these infections have been fatal.** Your doctor should test you for TB prior to treatment with Adalimumab-aaty, and monitor closely for signs and symptoms of TB throughout treatment with Adalimumab-aaty, regardless of your TB test results. Your doctor may choose to treat you with a medicine for TB if they feel you are at risk.

IMPORTANT SAFETY INFORMATION AND INDICATIONS

What is the most important information I should know about Adalimumab-aaty?

You should discuss treatment characteristics of Adalimumab-aaty with your doctor, including potential benefits and risks. Adalimumab-aaty is a TNF blocker medicine that can lower the ability of your immune system to fight infections. Notify your doctor if you have any kind of infection before you start taking Adalimumab-aaty.

- **Serious infections have happened in people taking adalimumab products, including tuberculosis (TB) and infections caused by viruses, fungi, or bacteria that have spread throughout the body. Some of these infections have been fatal.** Your doctor should test you for TB prior to treatment with Adalimumab-aaty, and monitor closely for signs and symptoms of TB throughout treatment with Adalimumab-aaty, regardless of your TB test results. Your doctor may choose to treat you with a medicine for TB if they feel you are at risk.
- **Cancer.** The chance of getting cancer may increase for children and adults taking TNF blockers, including adalimumab, including cases of unusual cancers. Some people have developed a rare type of cancer called hepatosplenic T-cell lymphoma, which is often fatal. Your chance of getting two types of skin cancer (basal cell and squamous cell) may increase while using TNF blockers, including adalimumab. Basal cell and squamous cell skin cancer are typically not life-threatening if treated. You should tell your doctor if you notice a bump or open sore that doesn't heal.

What should I tell my doctor BEFORE starting Adalimumab-aaty?

Give your doctor a complete description of your health, including the following:

- Current infection, treatment for infection, or symptoms of an infection
- Frequent infections or infections that don't resolve with treatment
- Diabetes
- Confirmed TB or close contact with someone who has TB, or were born in, lived in, or traveled where there is more risk for getting TB
- Current or prior residence in major river valleys where risk for getting certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis) is increased. These infections may happen or become more severe if you use Adalimumab-aaty. Ask your doctor about these infections to check if they are common in your area.
- Current or prior hepatitis B infection
- Scheduled for major surgery
- Current or prior cancer
- Disease that affects your nervous system that results in numbness or tingling in your extremities (multiple sclerosis, Guillain-Barré syndrome, etc.)
- Heart failure
- Recent or scheduled vaccines. While taking Adalimumab-aaty, patients may continue to receive vaccines except for live vaccines. Children should receive all recommended vaccines before starting Adalimumab-aaty.
- Known allergy to Adalimumab-aaty or any of its ingredients
- Current or planned pregnancy, or if you are currently breastfeeding or plan to
- If you have a baby while taking Adalimumab-aaty during your pregnancy. Tell your baby's doctor before your baby receives any vaccines

Also, tell your doctor about all the medicines you take. You should not take Adalimumab-aaty with ORENCIA® (abatacept), KINERET® (anakinra), REMICADE® (infliximab), ENBREL® (etanercept), CIMZIA® (certolizumab pegol), or SIMPONI® (golimumab). Tell your doctor if you have ever used RITUXAN® (rituximab), IMURAN® (azathioprine), or PURINETHOL® (mercaptopurine, 6-MP).

What should I watch for AFTER starting Adalimumab-aaty?

Adalimumab products, including Adalimumab-aaty, can cause serious side effects, including the following:

- **Serious infections.** Any infection caused by viruses, fungi, or bacteria, including TB. Common TB symptoms include cough, low-grade fever, weight loss, or loss of body fat and muscle.
- **Hepatitis B infection in carriers of the virus.** Common hepatitis B symptoms include muscle aches, feeling very tired, dark urine, skin or eyes that look yellow, little or no appetite, vomiting, clay-colored bowel movements, fever, chills, stomach discomfort, and skin rash.
- **Allergic reactions.** Common symptoms of a serious allergic reaction include hives, trouble breathing, and swelling of the face, eyes, lips, or mouth.
- **Nervous system problems.** Common signs and symptoms include numbness or tingling, problems with vision, weakness in your arms or legs, and dizziness.
- **Blood problems** (decreased blood cells that help fight infections or stop bleeding). Common symptoms include a fever that does not go away, bruising or bleeding very easily, or very pale skin tone.
- **Heart failure** (new or worsening). Common symptoms include shortness of breath, swelling in the ankles or feet, and sudden weight gain.
- **Immune reactions including a lupus-like syndrome.** Common symptoms include chest discomfort or pain that does not go away, shortness of breath, joint pain, or a rash on cheeks or arms that gets worse in the sun.

- **Liver problems.** Common symptoms include feeling very tired, skin or eyes that look yellow, poor appetite or vomiting, and pain on the right side of the stomach (abdomen). These problems can lead to liver failure and death.
- **Psoriasis** (new or worsening). Common symptoms include red scaly patches or raised, pus-filled bumps.

Call your doctor or get medical care right away if you develop any of the above symptoms.

Common side effects of adalimumab products include injection site reactions (redness, rash, swelling, itching, or bruising), **upper respiratory infections** (sinus infections), **headaches,** and **rash.** These are not all the possible side effects with adalimumab products, including Adalimumab-aaty. Tell your doctor if you have any side effect that bothers you or that does not go away.

Remember, tell your doctor right away if you have an infection or symptoms of an infection, including:

- Fever, sweats, or chills
- Muscle aches
- Cough
- Shortness of breath
- Blood in phlegm
- Weight loss
- Warm, red, or painful skin or sores on your body
- Diarrhea or stomach pain
- Burning when you urinate
- Urinating more often than normal
- Feeling very tired

Adalimumab-aaty is given by injection under the skin.

This is the most important information to know about Adalimumab-aaty. For more information, talk to your health care provider.

Indications

Adalimumab-aaty is a prescription medicine used:

- **To reduce the signs and symptoms of:**
 - **Moderate to severe rheumatoid arthritis (RA) in adults.** Adalimumab-aaty can be used alone, with methotrexate, or with certain other medicines.
 - **Moderate to severe polyarticular juvenile idiopathic arthritis (JIA) in children 2 years of age and older.** Adalimumab-aaty can be used alone or with methotrexate.
 - **Psoriatic arthritis (PsA) in adults.** Adalimumab-aaty can be used alone or with certain other medicines.
 - **Ankylosing spondylitis (AS) in adults.**
 - **Moderate to severe hidradenitis suppurativa (HS) in adults.**
- **To treat moderate to severe Crohn's disease (CD) in adults and children 6 years of age and older.**
- **To treat moderate to severe ulcerative colitis (UC) in adults.** It is not known if Adalimumab-aaty is effective in people who stopped responding to or could not tolerate anti-TNF medicines.
- **To treat moderate to severe chronic plaque psoriasis (Ps) in adults** who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.
- **To treat non-infectious intermediate, posterior, and panuveitis in adults.**

Please see the [Medication Guide](#), including **Boxed Warning**.

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