

## Medication Guide

AVTOZMA® (AV-TOZE'-MAH)  
(tocilizumab-anoh) injection  
for intravenous use  
AVTOZMA® (AV-TOZE'-MAH)  
(tocilizumab-anoh) injection  
for subcutaneous use

### What is the most important information I should know about AVTOZMA?

#### AVTOZMA can cause serious side effects including:

- 1. Serious Infections.** AVTOZMA is a medicine that affects your immune system. AVTOZMA can lower the ability of your immune system to fight infections. Some people have serious infections while taking AVTOZMA, 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 assess you for TB before starting AVTOZMA (except if you have COVID-19).

If you have COVID-19, your healthcare provider should monitor you for signs and symptoms of new infections during and after treatment with AVTOZMA.

Your healthcare provider should monitor you closely for signs and symptoms of TB during and after treatment with AVTOZMA.

- You should not start taking AVTOZMA if you have any kind of infection unless your healthcare provider says it is okay.

Before starting AVTOZMA, tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection, with or without a fever, such as:
  - 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
- are being treated for an infection.
- get a lot of infections or have infections that keep coming back.
- have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance for infections.
- have TB, or have been in close contact with someone with TB.
- live or have lived, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections (histoplasmosis, coccidiomycosis, or blastomycosis). These infections may happen or become more severe if you use AVTOZMA. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.
- have or have had hepatitis B.

After starting AVTOZMA, call your healthcare provider right away if you have any symptoms of an infection. AVTOZMA can make you more likely to get infections or make worse any infection that you have.

#### 2. Tears (perforation) of the stomach or intestines.

- Tell your healthcare provider if you have had diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people taking AVTOZMA get tears in their stomach or intestine. 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 have fever and new onset stomach-area pain that does not go away, and a change in your bowel habits.

#### 3. Liver problems (Hepatotoxicity):

Some people have experienced serious life-threatening liver problems, which required a liver transplant or led to death. Your healthcare provider may tell you to stop taking AVTOZMA if you develop new or worse liver problems during treatment with AVTOZMA.

Tell your healthcare provider right away if you have any of the following symptoms:

- feeling tired (fatigue)
- weakness

- lack of appetite for several days or longer (anorexia)
- yellowing of your skin or the whites of your eyes (jaundice)
- abdominal swelling and pain on the right side of your stomach-area
- light colored stools
- nausea and vomiting
- confusion
- dark “tea-colored” urine

**4. Changes in certain laboratory test results.** Your healthcare provider should do blood tests before you start receiving AVTOZMA. If you have rheumatoid arthritis (RA) or giant cell arteritis (GCA) your healthcare provider should do blood tests every 4 to 8 weeks after you start receiving AVTOZMA for the first 6 months 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 AVTOZMA:

- low neutrophil count. Neutrophils are white blood cells that help the body fight off bacterial infections.
- low platelet count. Platelets are blood cells that help with blood clotting and stop bleeding.
- increase in certain liver function tests.
- increase in blood cholesterol levels. You may also have changes in other laboratory tests, such as your blood cholesterol levels. Your healthcare provider should do blood tests to check your cholesterol levels 4 to 8 weeks after you start receiving AVTOZMA.

Your healthcare provider will determine how often you will have follow-up blood tests. Make sure you get all your follow-up blood tests done as ordered by your healthcare provider.

You should not receive AVTOZMA if your neutrophil or platelet counts are too low or your liver function tests are too high.

Your healthcare provider may stop your AVTOZMA treatment for a period of time or change your dose of medicine if needed because of changes in these blood test results.

**5. Cancer.** AVTOZMA may increase your risk of certain cancers by changing the way your immune system works. Tell your healthcare provider if you have ever had any type of cancer.

See “**What are the possible side effects with AVTOZMA?**” for more information about side effects.

### What is AVTOZMA?

AVTOZMA is a prescription medicine called an Interleukin-6 (IL-6) receptor antagonist. AVTOZMA is used:

- To treat adults with moderately to severely active rheumatoid arthritis (RA), after at least one other medicine called a Disease-Modifying Anti-Rheumatic Drug (DMARD) has been used and did not work well.
- To treat adults with giant cell arteritis (GCA).
- To treat people with active PJIA ages 2 and above.
- To treat people with active SJIA ages 2 and above.
- To treat people age 2 years and above who experience severe or life-threatening Cytokine Release Syndrome (CRS) following chimeric antigen receptor (CAR) T cell treatment.
- To treat hospitalized adults with coronavirus disease 2019 (COVID-19) receiving systemic corticosteroids and requiring supplemental oxygen or mechanical ventilation.
- AVTOZMA is not approved for subcutaneous use in people with CRS or COVID-19.

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

**Do not take AVTOZMA:** if you are allergic to tocilizumab products, or any of the ingredients in AVTOZMA. See the end of this Medication Guide for a complete list of ingredients in AVTOZMA.

**Before you receive AVTOZMA, tell your healthcare provider about all of your medical conditions, including if you:**

- have an infection. See “**What is the most important information I should know about AVTOZMA?**”
- have liver problems.
- have any stomach-area (abdominal) pain or been diagnosed with diverticulitis or ulcers in your stomach or intestines.
- have had a reaction to tocilizumab products or any of the ingredients in AVTOZMA before.
- have or had a condition that affects your nervous system, such as multiple sclerosis.

- have recently received or are scheduled to receive a vaccine:
  - All vaccines should be brought up-to-date before starting AVTOZMA, unless urgent treatment initiation is required.
  - People who take AVTOZMA should not receive live vaccines.
  - People taking AVTOZMA can receive non-live vaccines.
- plan to have surgery or a medical procedure.
- are pregnant or plan to become pregnant. AVTOZMA may harm your unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with AVTOZMA.
- are breastfeeding or plan to breastfeed. It is not known if AVTOZMA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take AVTOZMA.

**Tell your healthcare provider about all of the medicines you take**, including prescription, over-the-counter medicines, vitamins and herbal supplements. AVTOZMA and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- any other medicines to treat your RA. Taking AVTOZMA with these medicines may increase your risk of infection.
- medicines that affect the way certain liver enzymes work. Ask your healthcare provider if you are not sure if your medicine is one of these.

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

### **How will I receive AVTOZMA?**

#### **Into a vein (IV or intravenous infusion) for Rheumatoid Arthritis, Giant Cell Arteritis, PJIA, SJIA, CRS or COVID-19:**

- If your healthcare provider prescribes AVTOZMA as an IV infusion, you will receive AVTOZMA from a healthcare provider through a needle placed in a vein in your arm. The infusion will take about 1 hour to give you the full dose of medicine.
- For rheumatoid arthritis, giant cell arteritis or PJIA you will receive a dose of AVTOZMA about every 4 weeks.
- For SJIA you will receive a dose of AVTOZMA about every 2 weeks.
- For CRS you will receive a single dose of AVTOZMA, and if needed, additional doses.
- For COVID-19, you will receive a single dose of AVTOZMA, and if needed one additional dose.
- While taking AVTOZMA, you may continue to use other medicines that help treat your rheumatoid arthritis, PJIA, SJIA or COVID-19 such as methotrexate, non-steroidal anti-inflammatory drugs (NSAIDs) and prescription steroids, as instructed by your healthcare provider.
- Keep all of your follow-up appointments and get your blood tests as ordered by your healthcare provider.

#### **Under the skin (SC or subcutaneous injection) for Rheumatoid Arthritis, Giant Cell Arteritis, PJIA or SJIA:**

- **See the Instructions for Use at the end of this Medication Guide for instructions about the right way to prepare and give your AVTOZMA injections at home.**
- AVTOZMA is available as a single-dose Prefilled Syringe or single-dose Prefilled Autoinjector.
- You may also receive AVTOZMA as an injection under your skin (subcutaneous). If your healthcare provider decides that you or a caregiver can give your injections of AVTOZMA at home, you or your caregiver should receive training on the right way to prepare and inject AVTOZMA. Do not try to inject AVTOZMA until you have been shown the right way to give the injections by your healthcare provider.
- For PJIA or SJIA, you may self-inject with the Prefilled Syringe or Prefilled Autoinjector, or your caregiver can give you AVTOZMA, if both your healthcare provider and parent/legal guardian find it appropriate.
- Your healthcare provider will tell you how much AVTOZMA to use and when to use it.

### **What are the possible side effects with AVTOZMA?**

#### **AVTOZMA can cause serious side effects, including:**

- See **“What is the most important information I should know about AVTOZMA?”**
- **Hepatitis B infection** in people who carry the virus in their blood. If you are a carrier of the hepatitis B virus (a virus that affects the liver), the virus may become active while you use AVTOZMA. Your healthcare provider may

do blood tests before you start treatment with AVTOZMA and while you are using AVTOZMA. Tell your healthcare provider if you have any of the following symptoms of a possible hepatitis B infection:

- |                   |                                |                         |
|-------------------|--------------------------------|-------------------------|
| ○ 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 AVTOZMA. These reactions can happen with any infusion or injection of AVTOZMA, even if they did not occur with an earlier infusion or injection. Stop taking AVTOZMA, contact your healthcare provider, and get emergency help right away if you have any of the following signs of a serious allergic reaction:
  - swelling of your face, lips, mouth, or tongue
  - trouble breathing
  - wheezing
  - severe itching
  - skin rash, hives, redness, or swelling outside of the injection site area
  - dizziness or fainting
  - fast heartbeat or pounding in your chest (tachycardia)
  - sweating
- **Nervous system problems.** While rare, Multiple Sclerosis has been diagnosed in people who take AVTOZMA. It is not known what effect AVTOZMA may have on some nervous system disorders.

**The most common side effects of AVTOZMA include:**

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

**Tell your healthcare provider about any side effect that bothers you or does not go away. These are not all the possible side effects of AVTOZMA. For more information, ask your healthcare provider or pharmacist.**

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

**General information about the safe and effective use of AVTOZMA.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not give AVTOZMA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about AVTOZMA that is written for health professionals.

**What are the ingredients in AVTOZMA?**

Active ingredient: tocilizumab-anoh.

Inactive ingredients of Intravenous AVTOZMA: histidine, L-histidine hydrochloride monohydrate, methionine, polysorbate 80, threonine, and water for Injection.

Inactive ingredients of Subcutaneous AVTOZMA: histidine, L-histidine hydrochloride monohydrate, methionine, polysorbate 80, threonine, and water for Injection.

Manufactured by: CELLTRION, Inc., 23, Academy-ro, Yeonsu-gu, Incheon, 22014, Republic of Korea  
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**Instructions for Use**  
**AVTOZMA® (AV-TOZE'-MAH)**  
**(tocilizumab-anoh)**  
**Injection, For Subcutaneous Use**  
**Single-dose Prefilled Syringe**

Read and follow the Instructions for Use that come with your AVTOZMA Prefilled Syringe before you start using it and each time you get a refill. There may be new information. Before you use AVTOZMA, make sure your healthcare provider shows you the right way to use it.

**Important Information**

- **Do not** remove the prefilled syringe cap until you are ready to inject AVTOZMA.
- **Do not** try to take apart the prefilled syringe at any time.
- **Do not** reuse the same syringe.
- **Do not** shake the prefilled syringe.
- **Do not** use the prefilled syringe if it has been dropped or damaged.

**Storing AVTOZMA**

- Store the unused prefilled syringe in the original carton in a refrigerator between 36°F to 46°F (2°C to 8°C). Do not freeze.
- When removed from the refrigerator, AVTOZMA can be stored up to 3 weeks at or below 77°F (25°C). If not used within the 3 weeks, AVTOZMA should be thrown away (discarded).
- Keep the prefilled syringe out of direct sunlight.
- **Do not** remove the prefilled syringe from its original carton during storage.
- **Do not** leave the prefilled syringe unattended.
- Keep the prefilled syringe out of the reach of children.

Parts of your Prefilled Syringe (See Figure A).

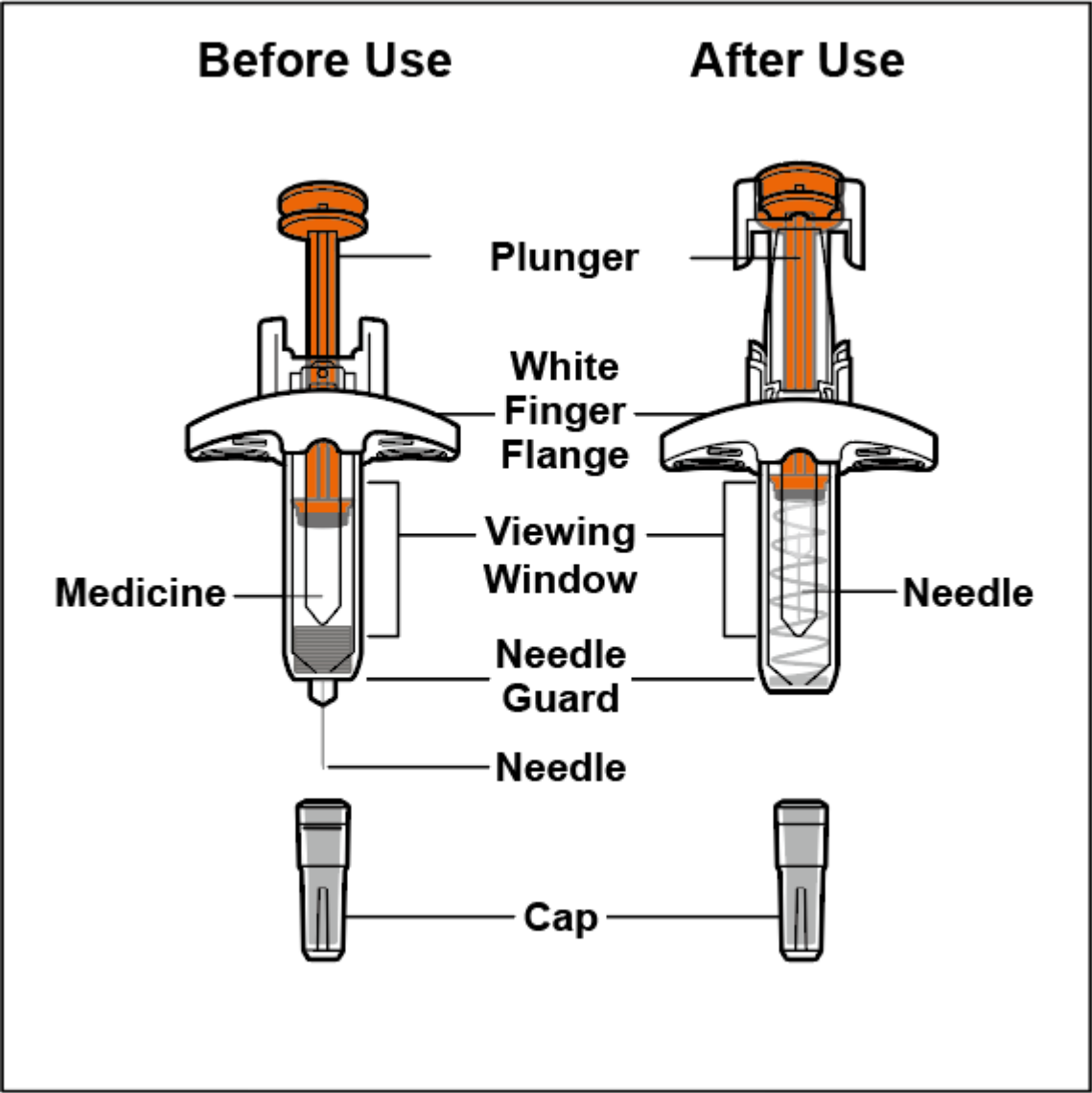


Figure A

## Preparing for the Injection

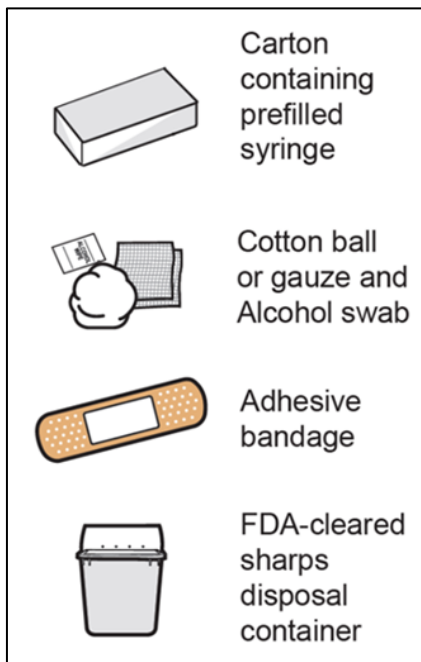


Figure B

### 1. Gather the supplies for the injection.

- Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- Take the carton containing the prefilled syringe out of the refrigerator.
- Make sure you have the following supplies (see **Figure B**):
  - Carton containing AVTOZMA prefilled syringe

#### Not included in the carton:

- Cotton ball or gauze
- Adhesive bandage
- FDA-cleared sharps disposal container
- Alcohol swab

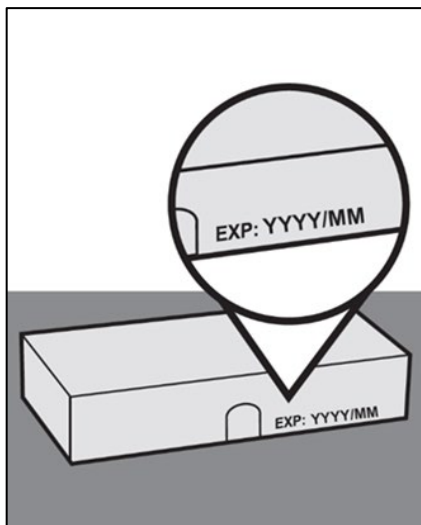


Figure C

### 2. Inspect the carton (see Figure C).

- Look at the carton and make sure you have the correct medicine and dose strength. (AVTOZMA)
  - Check the expiration (EXP) date on the carton to make sure the date has not passed.
- **Do not** use the prefilled syringe if the expiration (EXP) date has passed.
  - **Do not** use the prefilled syringe if the carton looks like it has been opened or damaged if you are opening the carton for the first time and check to make sure that it is properly sealed.

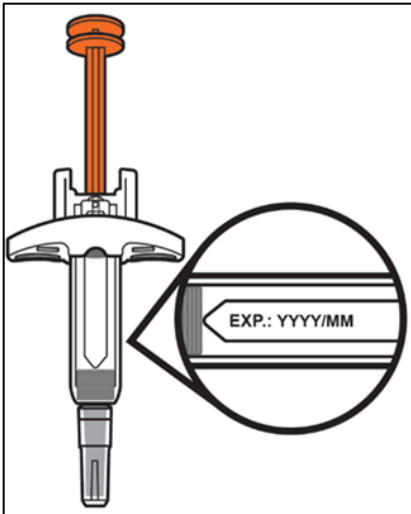


Figure D

### 3. Inspect the Prefilled Syringe.

- a. Open the carton and remove 1 single-dose prefilled syringe from the carton. Return any remaining AVTOZMA prefilled syringes in the carton to the refrigerator.
- b. Check the expiration (EXP) date on the AVTOZMA prefilled syringe (**see Figure D**).
  - **Do not** use the prefilled syringe if the expiration (EXP) date has passed. If the expiration (EXP) date has passed, safely throw away (dispose of) the prefilled syringe in your FDA-cleared sharps disposal container and get a new one.
- c. Check the prefilled syringe to make sure it is not damaged and shows no sign of leakage.
  - **Do not** use the prefilled syringe if it has been dropped, damaged, or has leaked.

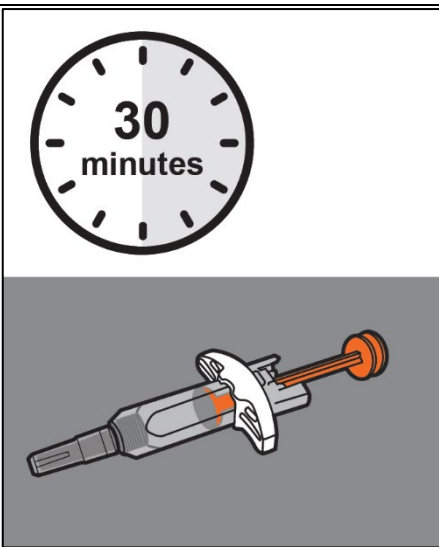


Figure E

### 4. Wait 30 minutes.

- a. Leave the prefilled syringe outside of the carton at room temperature between 68°F to 77°F (20°C to 25°C) for 30 minutes to allow it to warm up (**see Figure E**).
  - **Do not** warm the prefilled syringe using heat sources such as hot water or a microwave.
  - **Do not** leave the prefilled syringe in the direct sunlight.
  - **Do not** remove the cap while allowing your prefilled syringe to reach room temperature.
  - If the prefilled syringe does not reach room temperature, this could cause discomfort and make it hard to push the plunger.

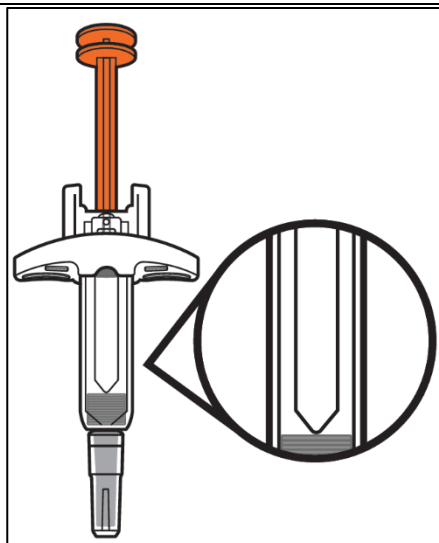


Figure F

### 5. Inspect the medicine.

- a. Hold your AVTOZMA with the cap pointing down.
- b. Look at the medicine and confirm that the liquid is clear, to slightly pearly and colorless to yellow and does not contain any particles or flakes (**see Figure F**).
  - **Do not** use the prefilled syringe if the liquid is discolored, cloudy, or has particles or flakes in it. Safely dispose of the prefilled syringe in a FDA-cleared sharps disposal container and use a new one.
  - Air bubbles are normal.



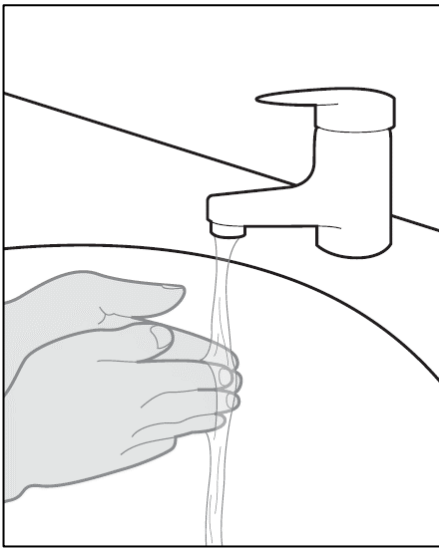


Figure G

**6. Wash your hands.**

- a. Wash your hands with soap and water and dry them thoroughly (see **Figure G**).

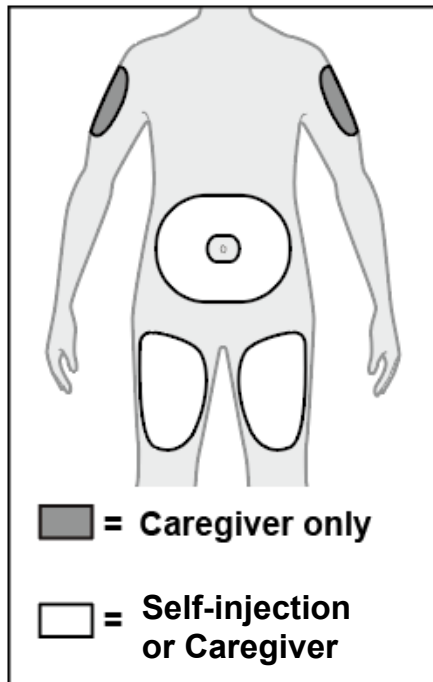


Figure H

**7. Choose an injection site (see Figure H).**

- a. You may inject into
- The front of the thighs
  - The stomach (abdomen), except for the 2 inches (5 cm) around the belly button.
  - The outer area of the upper arm (only if you are a caregiver).
- **Do not** inject into the upper arm by yourself.
  - Choose a different injection site for each new injection at least 1 inch (2.5 cm) 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.

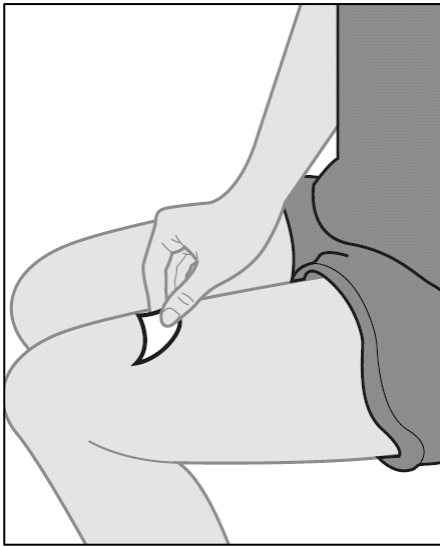


Figure I

#### 8. Clean the injection site.

- a. Wipe the injection site with an alcohol swab and let it air dry for about 10 seconds (see **Figure I**). This will 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.

### Giving the Injection

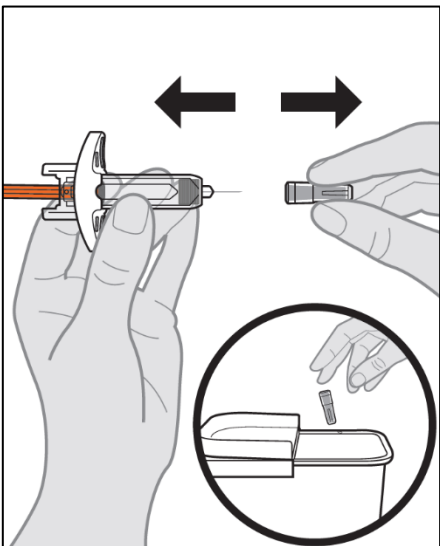


Figure J

#### 9. Remove the cap.

- a. Hold the prefilled syringe by the syringe body using 1 hand. Gently pull the cap straight off with the other hand (see **Figure J**).  
 Note: If you cannot remove the cap, you should ask a caregiver for help or contact your healthcare provider.
  - **Do not** hold the plunger while removing the cap.
  - You may see a drop of liquid at the tip of the needle. This is normal.
  - If the prefilled syringe is not used within 5 minutes of needle cap removal, the prefilled syringe should be thrown away (disposed of) in the puncture resistant container or sharps container and a new prefilled syringe should be used.
- b. Throw away (dispose of) the cap right away in your FDA-cleared sharps disposal container (see **step 14** and Throw away (**dispose of**) prefilled syringe and **Figure N**)
  - **Do not** re-cap the prefilled syringe.
  - **Do not** touch the needle shield at the tip of the prefilled syringe to avoid accidental needle stick injury.

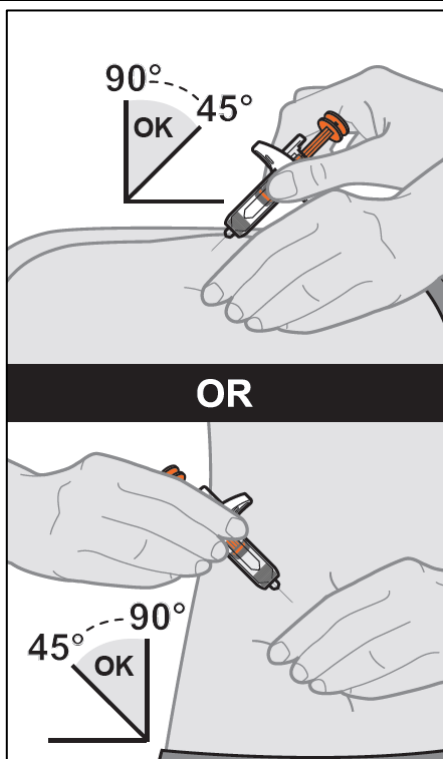


Figure K

#### 10. Insert the prefilled syringe into the injection site.

- a. Gently pinch a fold of skin at the injection site with 1 hand.

Note: Pinching the skin is important to make sure that you inject under the skin (into fatty tissue) but not any deeper (into muscle).

- b. With a quick and “dart-like” motion, insert the Needle completely into the fold of skin at a 45 to 90-degree angle (see **Figure K**).

Note: 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.

- **Do not** touch the plunger while inserting the needle into the skin.
- **Do not** pull back on the plunger rod at any time.

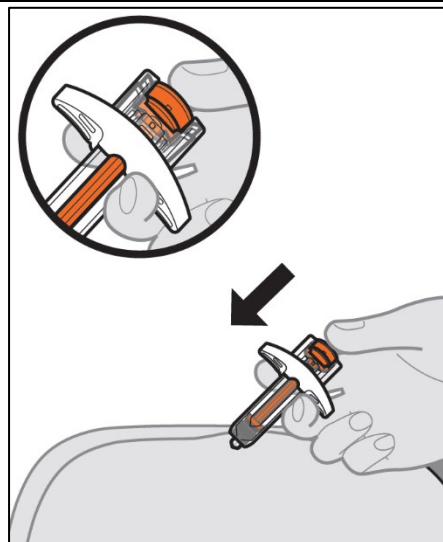


Figure L

#### 11. Give the injection.

- a. After the needle is inserted, release the pinch.
  - b. Slowly push the plunger all the way down until the full dose of medicine gets injected, and the syringe is empty (see **Figure L**).
- **Do not** change the position of the prefilled syringe after the injection has started.
  - If the plunger is not fully pressed, the needle guard will not extend to cover the needle when it is removed.
  - If the needle is not covered, proceed carefully to dispose of the syringe (see step **14. Throw away (dispose of) prefilled syringe.**

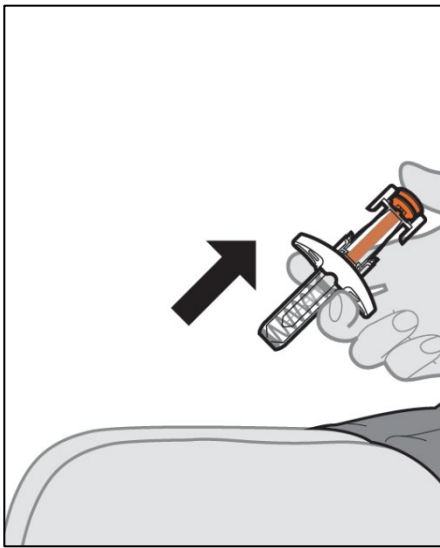


Figure M

## 12. Remove the prefilled syringe from the injection site.

- a. After the prefilled syringe is empty, remove the needle from the injection site and release the plunger until the entire needle is covered by the guard (see **Figure M**).
  - Some bleeding may occur (see step **13. Care for the injection site**).
  - In case of skin contact with medicine, wash the area that touched the medicine with water.
  - **Do not** reuse the prefilled syringe.

## After the Injection

### 13. Care for the injection site.

- a. If a little bleeding occurs, treat the injection site by gently pressing, not rubbing, a cotton ball or gauze to the site and apply an adhesive bandage if needed.
  - **Do not** rub the injection site.

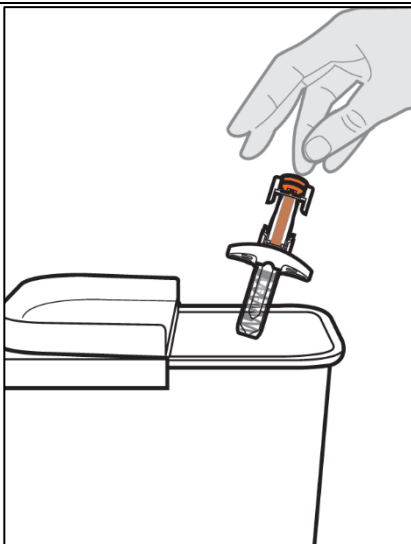


Figure N

## 14. Throw away (dispose of) the prefilled syringe.

- a. Put the used prefilled syringe and other supplies in your FDA-cleared sharps disposal container right away after use (see **Figure N**).

Note: If your injection is given by another person, this person must also be careful when removing the prefilled syringe and disposing of it to prevent accidental needle stick injury and passing infection.

- **Do not** re-use the prefilled syringe.
- **Do not** put the cap back onto the prefilled syringe.
- **Do not** throw away (dispose of) your used sharps disposal container in your household trash.
- **Do not** recycle your used sharps disposal container.
- Keep the AVTOZMA prefilled syringe and disposal container out of the reach of children.

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 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 prefilled 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>.

## 15. Record your injection.

**a.** Write the date, time, and specific part of your body where you injected yourself.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.  
Revised: 07/2025

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**Instructions for Use**  
**AVTOZMA® (AV-TOZE'-MAH)**  
**(tocilizumab-anoh)**  
**Injection, For Subcutaneous Use**  
**Single-dose Prefilled Autoinjector**

Read and follow the Instructions for Use that come with your AVTOZMA prefilled autoinjector before you start using it and each time you get a refill. There may be new information. Before you use AVTOZMA, make sure your healthcare provider shows you the right way to use it.

**Important Information**

- **Do not** remove the prefilled autoinjector cap until you are ready to inject AVTOZMA.
- **Do not** try to take apart the prefilled autoinjector at any time.
- **Do not** reuse the same prefilled autoinjector.
- **Do not** inject through clothing.
- **Do not** use the prefilled autoinjector if it has been dropped or damaged.

**Storing AVTOZMA**

- Store the unused prefilled autoinjector in the original carton in a refrigerator between 36°F to 46°F (2°C to 8°C). **Do not** freeze.
- When removed from the refrigerator, AVTOZMA can be stored up to 3 weeks at or below 77°F (25°C). If not used within the 3 weeks, AVTOZMA should be thrown away (discarded).
- Keep the prefilled autoinjector out of direct sunlight.
- **Do not** remove the prefilled autoinjector from its original carton during storage.
- **Do not** leave the prefilled autoinjector unattended.
- Keep the prefilled autoinjector out of the reach of children.

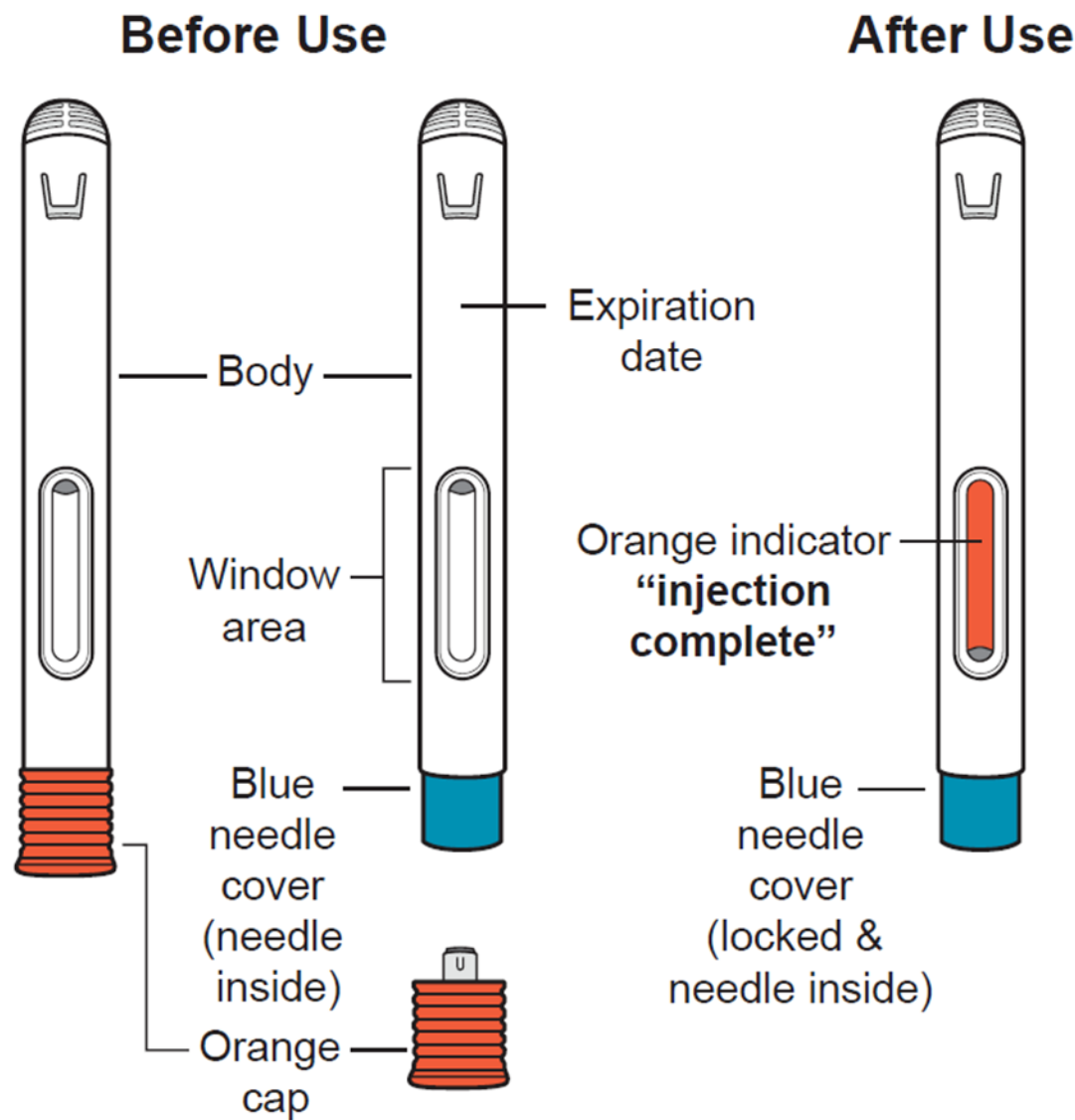


Figure A

## Preparing for the Injection

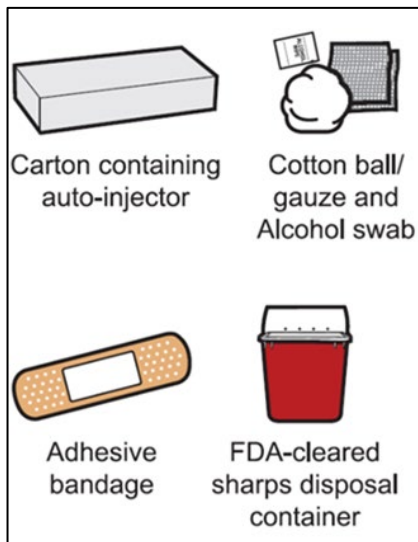


Figure B

### 1. Gather the supplies for the injection.

- Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- Take the carton containing the prefilled autoinjector out of the refrigerator.
- Make sure you have the following supplies (see Figure B):
  - Carton containing AVTOZMA prefilled autoinjector

#### Not included in the carton:

- Cotton ball or gauze
- Adhesive bandage
- FDA-cleared Sharps disposal container
- Alcohol swab

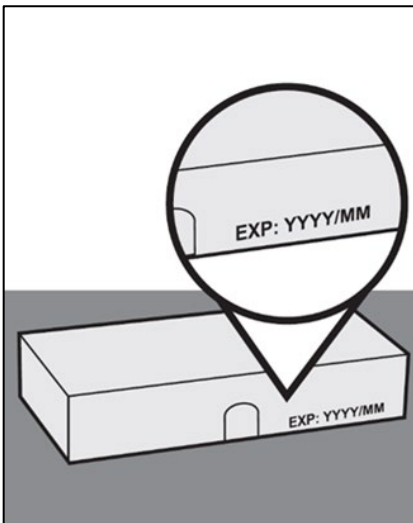


Figure C

### 2. Inspect the carton (see Figure C).

- Look at the carton and make sure you have the correct medicine and dose strength. (AVTOZMA)
- Check the expiration (EXP) date on the carton to make sure the date has not passed.
  - **Do not** use the prefilled autoinjector if the expiration (EXP) date has passed.
  - If you are opening the carton for the first time, check to make sure that it is properly sealed.
  - **Do not** use the prefilled autoinjector if the carton looks like it has been opened or damaged.



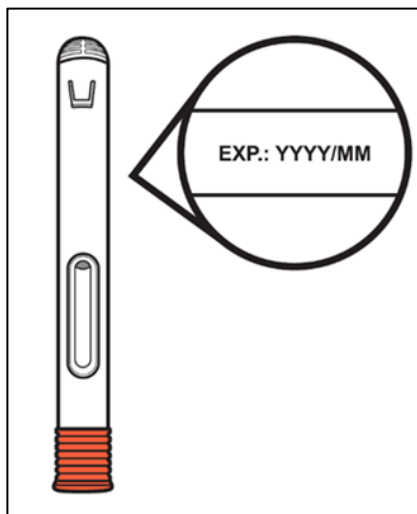


Figure D

### 3. Inspect the Prefilled autoinjector.

- a. Open the carton and remove one single-dose prefilled autoinjector from the carton. Return any remaining AVTOZMA prefilled autoinjectors in the box to the refrigerator.
- b. Check the expiration (EXP) date on the AVTOZMA prefilled autoinjector (see Figure D).
  - **Do not** use the prefilled autoinjector if the expiration (EXP) date has passed. If the expiration (EXP) date has passed, safely throw away (dispose of) the prefilled autoinjector in your sharps disposal container and get a new one.
- c. Check the prefilled autoinjector to make sure it is not damaged and shows no sign of leakage.
  - **Do not** use the prefilled autoinjector if it has been dropped, damaged, or has leaked.

Note: A small gap between the orange cap and injector body is normal.

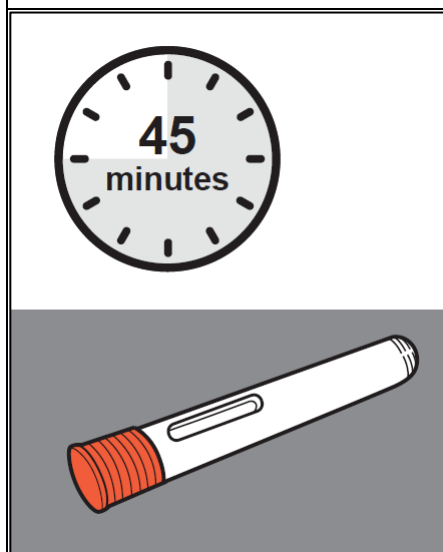


Figure E

### 4. Wait 45 minutes.

- a. Leave the prefilled autoinjector outside of the carton at room temperature between 68°F to 77°F (20°C to 25°C) for 45 minutes to allow it to warm up (see Figure E).
  - **Do not** warm the prefilled autoinjector using heat sources such as hot water or a microwave.
  - **Do not** leave the prefilled autoinjector in the direct sunlight.
  - **Do not** remove the cap while allowing your prefilled autoinjector to reach room temperature.
  - If the prefilled autoinjector does not reach room temperature, this could cause discomfort.

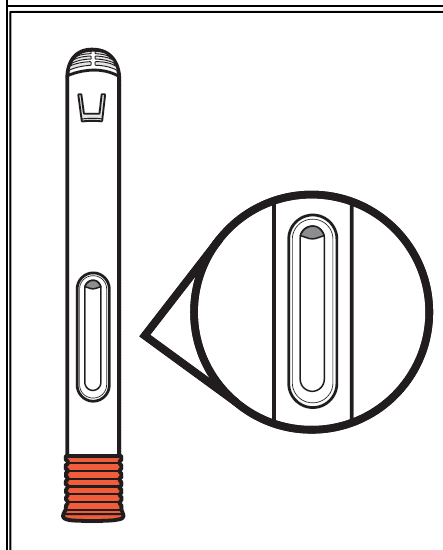


Figure F

### 5. Inspect the medicine.

- a. Hold your AVTOZMA with the cap pointing down.
- b. Look at the medicine and confirm that the liquid is clear, to slightly pearly and colorless to yellow and does not contain any particles or flakes (see Figure F).
  - **Do not** use the prefilled autoinjector if the liquid is discolored, cloudy, or has particles or flakes in it. Safely dispose of the prefilled autoinjector in a FDA-cleared sharps disposal container and use a new one.
  - Air bubbles are normal.

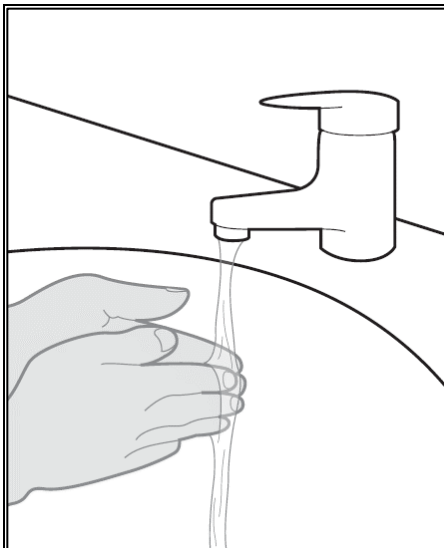


Figure G

## 6. Wash your hands.

- a. Wash your hands with soap and water and dry them thoroughly (see **Figure G**).

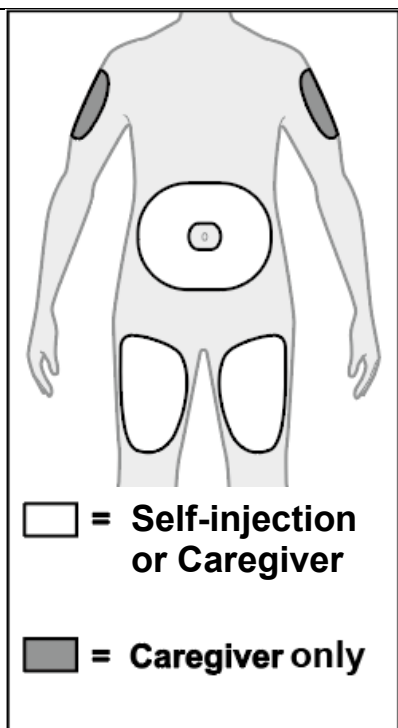


Figure H

## 7. Choose an injection site (see **Figure H**).

- a. You may inject into
  - The front of the thighs
  - The stomach (abdomen), except for the 2 inches (5 cm) around the belly button.
  - The outer area of the upper arm (only if you are a caregiver).
- **Do not** inject into the upper arm by yourself.
- Choose a different injection site for each new injection at least 1 inch (2.5 cm) 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.

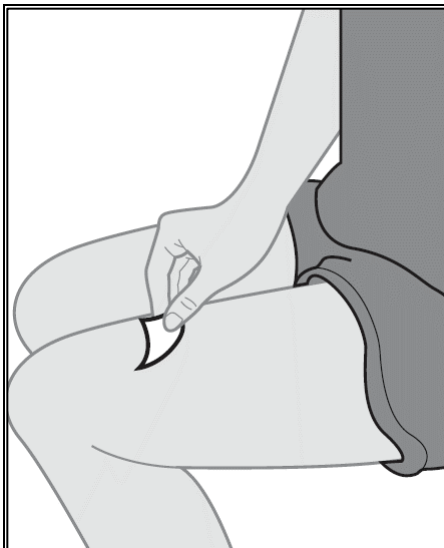


Figure I

#### 8. Clean the injection site.

- a. Wipe the injection site with an alcohol swab and let it air dry for about 10 seconds (see **Figure I**). This will 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.

### Giving the Injection

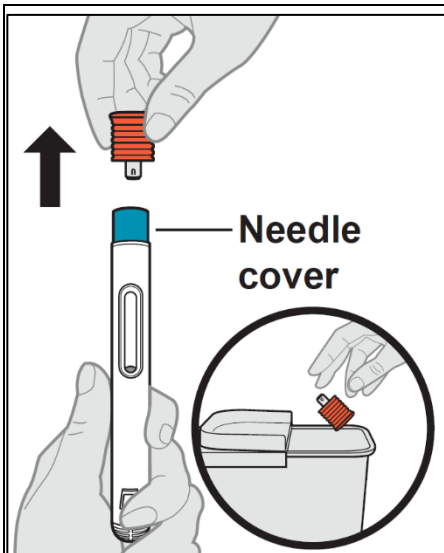


Figure J

#### 9. Remove the cap.

- a. Hold the prefilled autoinjector by the injector body with the cap on top using 1 hand.  
Gently pull the cap straight off with the other hand (see **Figure J**).  
Note: If you cannot remove the cap, you should ask a caregiver for help or contact your healthcare provider.
- b. Throw away (dispose of) the cap right away in your FDA-cleared sharps disposal container (see **step 14** and **Figure O**)
  - **Do not** re-cap the prefilled autoinjector.
  - **Do not** touch the needle shield at the tip of the prefilled autoinjector to avoid accidental needle stick injury.
  - After you remove the cap, the prefilled autoinjector is ready for use. If the prefilled autoinjector is not used within 3 minutes of cap removal, throw away the prefilled autoinjector in a FDA-cleared sharps disposal container and use a new prefilled autoinjector.

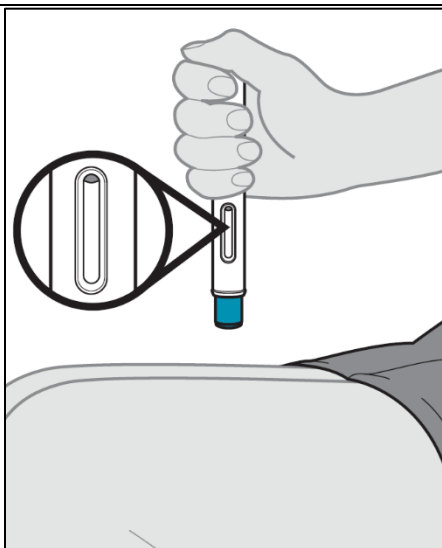


Figure K

**10. Place the prefilled autoinjector on the injection site.**

- a. Hold the prefilled autoinjector comfortably in 1 hand so that you can see the window (see **Figure K**).
- b. Without pinching or stretching the skin, place the prefilled autoinjector against the skin at a 90-degree angle (see **Figure L**).

Note: 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

- **Do not** inject into muscle or a blood vessel.

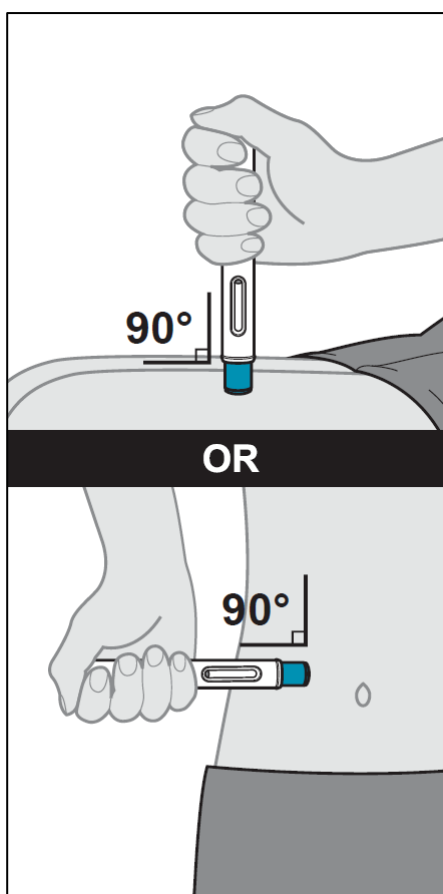


Figure L

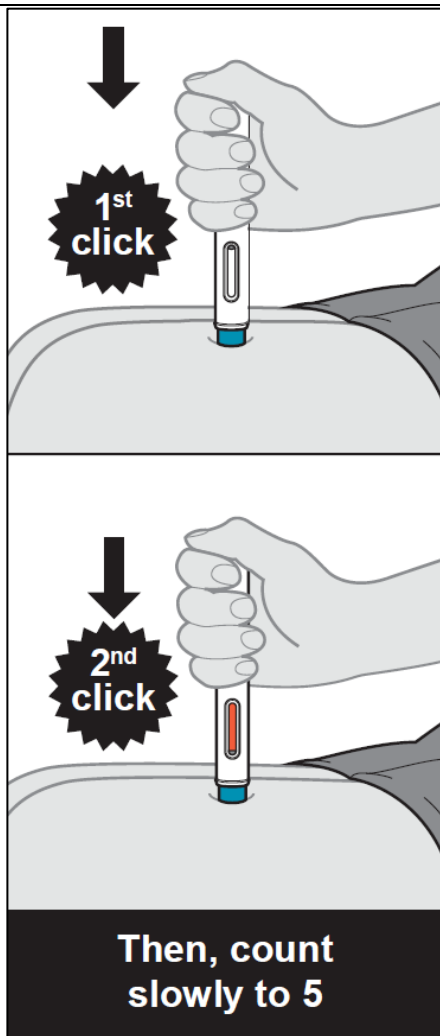


Figure M

#### 11. Give the injection.

- a. Firmly press the prefilled autoinjector into the skin to begin the injection.
- b. When the injection starts you will hear the 1<sup>st</sup> “click” and the orange indicator will begin to fill the window (see **Figure M**).
- c. Keep holding the prefilled autoinjector firmly against the skin and listen for the 2<sup>nd</sup> “click”.
- d. After you hear the 2<sup>nd</sup> “click”, continue to hold the prefilled autoinjector firmly against the skin and **count slowly to 5** to make sure you inject the full dose (see **Figure M**).
- e. Watch the orange indicator until it stops moving and has reached the end of the window to be sure the full dose of medicine is injected.

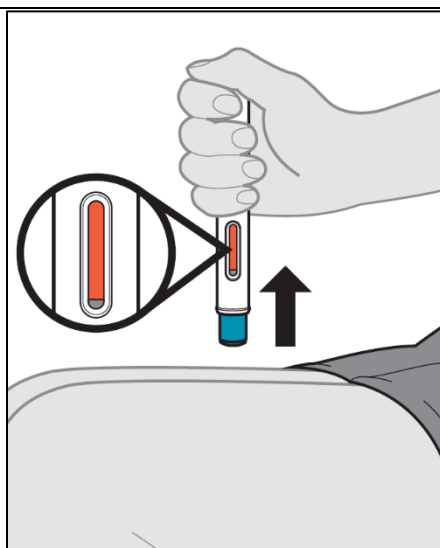


Figure N

#### 12. Remove the prefilled autoinjector from the injection site.

- a. When the orange indicator has stopped moving, lift the prefilled autoinjector straight off of the injection site at a 90-degree angle to remove the needle from the skin.
- The needle cover will automatically move out and lock into place covering the needle (see **Figure N**).

Note: If the window has not turned completely orange or if the medicine is still injecting, this means you have not received a full dose. Carefully place the prefilled autoinjector into the FDA-cleared sharps disposal container and call your healthcare provider immediately.

- **Do not** touch the needle cover of the prefilled autoinjector.
- **Do not** try to re-use the prefilled autoinjector.
- **Do not** repeat the injection with another prefilled autoinjector.

## After the Injection

### 13. Care for the injection site.

- a. If a little bleeding occurs, treat the injection site by gently pressing, not rubbing, a cotton ball or gauze to the site and apply an adhesive bandage if needed.
  - **Do not** rub the injection site



Figure O

### 14. Dispose of AVTOZMA.

- a. Put the used prefilled autoinjector and other supplies in your FDA-cleared sharps disposal container right away after use (see **Figure O**).

Note: If your injection is given by another person, this person must also be careful when removing the prefilled autoinjector and disposing of it to prevent accidental needle stick injury and passing infection.

- **Do not** re-use the prefilled autoinjector.
- **Do not** put the cap back onto the prefilled autoinjector.
- **Do not** dispose of your used sharps disposal container in your household trash.
- **Do not** recycle your used sharps disposal container.
- Keep the AVTOZMA prefilled autoinjector and disposal container out of the reach of children.

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 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>.

### 15. Record your injection.

- a. Write the date, time, and specific part of your body where you injected yourself.

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