

Instructions for Use

Tyenne[®]
tocilizumab-aazg

Injection
162 mg / 0.9 mL
For Subcutaneous Use Only
Single-dose autoinjector



Read these instructions carefully
before using your Tyenne autoinjector.

Read and follow the Instructions for Use that come with your TYENNE autoinjector before you start using it and each time you get a refill. There may be new information. This information does not replace talking to your healthcare provider about your medical condition or treatment.

If you have any questions about using your TYENNE autoinjector, please call your healthcare provider or Company at 1-833-522-4227.

Important information

- Read the Medication Guide that comes with your autoinjector for important information you need to know before using it.
- Before you use the autoinjector for the first time, make sure your healthcare provider shows you the right way to use it.
- **Do not** try to take apart the TYENNE autoinjector at any time.
- Always inject TYENNE the way your healthcare provider taught you to.

Using the TYENNE autoinjector

- The autoinjector is for self-injection or administration with the help of a caregiver.
- The autoinjector is for use at home.
- **When injecting TYENNE, children may self-inject if both the healthcare provider and caregiver find it appropriate.**
- **Do not** reuse the autoinjector. The autoinjector is for single-dose (1-time) use only.
- **Do not** share your autoinjector with another person. You may give another person an infection or get an infection from them.
- **Do not** remove the autoinjector clear cap until you are ready to inject.
- **Do not** use the autoinjector if it shows any signs of damage or if it has been dropped.

Storing TYENNE autoinjectors

- Store TYENNE in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Store unused autoinjectors in the original carton to protect from light.
- **Do not** freeze TYENNE. **Do not** use TYENNE if frozen. Throw away (dispose of) in a sharps disposal container.
- **Do not** expose TYENNE to heat or direct sunlight.
- Keep the autoinjector out of the reach of children.
- TYENNE may be stored at room temperature at or below 77°F (25°C) in the original carton for up to 14 days. Throw away (dispose of) TYENNE in a sharp disposal container if it has been out of the refrigerator more than 14 days. After being stored at room temperature, do not place

it back in the refrigerator.

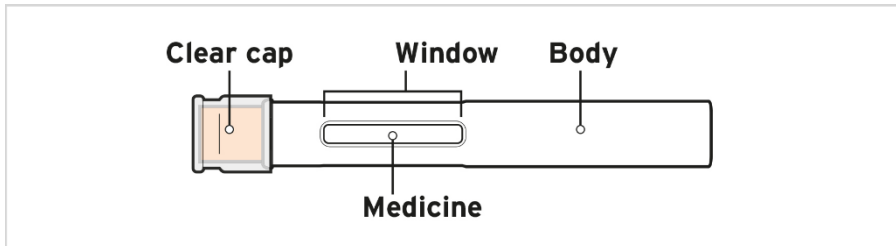
See the Medication Guide for more information.

Traveling with TYENNE autoinjector

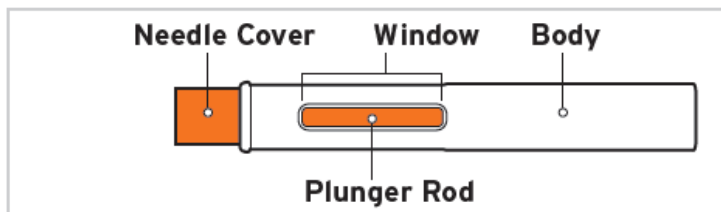
- When travelling on an airplane, always check with your airline and your healthcare provider about bringing injectable medicine with you. Always carry TYENNE in your carry-on luggage because the airplane luggage area can be very cold and TYENNE could freeze.

Your TYENNE autoinjector

Before Use



After Use



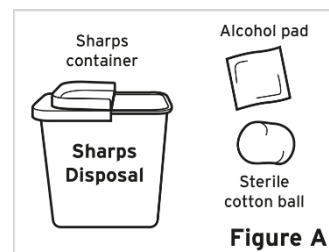
Step 1

Prepare for your injection

1.1. Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.

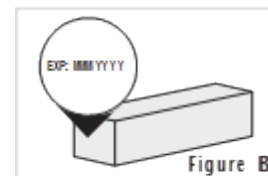
1.2. Gather the following supplies (not included) (see **Figure A**):

- A sterile cotton ball or gauze
- An alcohol pad
- An FDA-cleared sharps disposal container (see **Step 8**, “**Throw away your autoinjector**”).



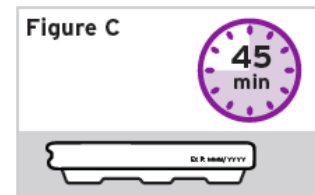
1.3. Remove the carton containing the autoinjector from the refrigerator.

1.4. Check the expiration date on the carton to make sure the date has not passed (see **Figure B**). **Do not** use the autoinjector if the expiration date has passed.



1.5. Remove the sealed tray from the carton. Check the sealed tray for any signs of damage, and make sure the expiration date has not passed. **Do not** use if the expiration date on the tray has passed, because it may not be safe. **Do not** use the autoinjector if the tray looks **damaged** or like it has been **opened**.

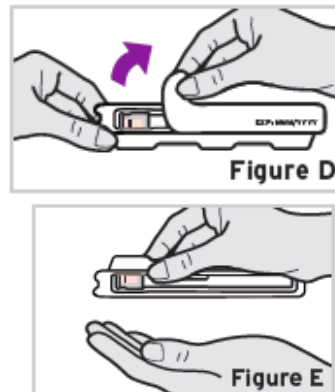
1.6. Let the sealed tray sit on the prepared surface for 45 minutes before use to allow the medicine in the autoinjector to reach room temperature (see **Figure C**).



Note: Not doing so could cause your injection to feel uncomfortable and it could take longer to inject.

Do not warm in any other way, such as in a microwave, hot water, or direct sunlight.

1.7. Peel the seal off of the tray (see **Figure D**) and turn the tray upside down to remove the single-dose autoinjector (see **Figure E**).

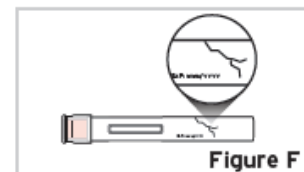


Do not remove the clear cap of the autoinjector until you are ready to inject to avoid injury.

Step 2

Check your autoinjector

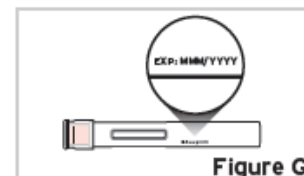
2.1 Check the autoinjector to make sure it is not cracked or damaged (see **Figure F**).



Do not use if the autoinjector shows signs of damage or if it has been dropped.

2.2 Check the autoinjector label to make sure that:

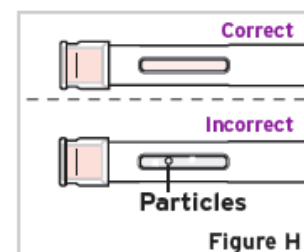
- The name on the autoinjector says TYENNE
- The expiration date (EXP) on the autoinjector has not passed (see **Figure G**)



Do not use the autoinjector if the name on the label is not TYENNE or the expiration date on the label has passed.

2.3 Look at the medicine in the viewing window.

Make sure it is **clear and colorless to pale yellow** and does not contain flakes or particles (see **Figure H**).



Note: Air bubbles in the medicine are normal.

Do not inject if the liquid is cloudy, discolored, or has lumps or particles in it because it may not be safe to use.

Step 3 Wash your hands

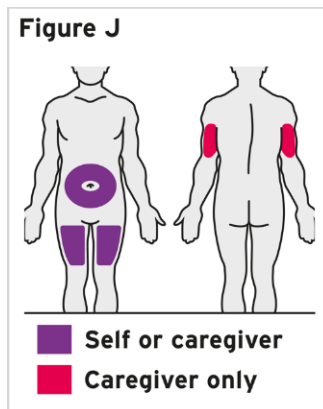
3.1 Wash your hands well with soap and water, then dry them with a clean towel (see **Figure I**).



Step 4 Choose the injection site

4.1 If you are giving yourself the injection, you can use:

- The front of your upper thigh
- The belly (abdomen), except within 2 in (5 cm) around the belly button (navel)



If a caregiver is giving the injection, they can use the outer area of the upper arm (see **Figure J**).

Note: Choose a different site for each injection to reduce redness, irritation, or other skin problems.

Do not inject into skin that is sore (tender), bruised, red, hard, scaly, or has lesions, moles, scars, or stretch marks or tattoos.

Do not use the autoinjector through clothing.

Step 5 Clean the injection site

5.1 Wipe the skin where you want to inject with an alcohol pad to clean it (see **Figure K**). Let the skin dry.

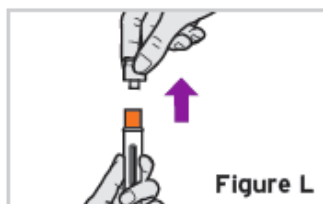
Do not blow on or touch the site after cleaning.



Step 6 Give your injection

6.1 When you are ready to inject, hold the autoinjector in one hand with the clear cap on top, pointing straight up.

Using your other hand, firmly pull the clear cap straight off without twisting (see **Figure L**).



Note: Use the autoinjector **within 3 minutes** after removing the cap to avoid contamination.

Do not try to recap the needle at any time, even at the end of the injection.

Do not touch the needle cover (the orange part located at the tip of the autoinjector) because this might cause an accidental needle stick.

6.2 Throw away the clear cap in a sharps disposal container.

6.3 Rotate the autoinjector so that the orange needle cover points downwards.

6.4 Position your hand on the autoinjector so that you can see the window.

6.5 Place the needle cover flat against your skin at a 90-degree angle (see **Figure M**).

Note: To make sure you inject under the skin (into fatty tissue), **do not** hold the autoinjector at an angle.

Do not pinch your skin.

To make sure you inject the full dose, read all of the steps from 6.6 to 6.9 before you start:

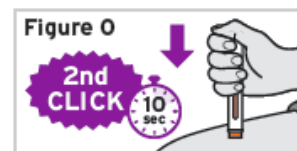
6.6 In a single motion, push **and hold** the autoinjector firmly against your skin until you hear a **first click**. This means the injection has started (see **Figure N**).

The orange plunger rod will move through the window during the injection.

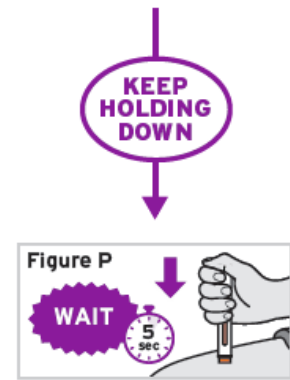


KEEP HOLDING DOWN

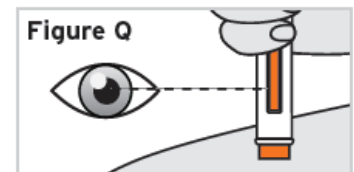
6.7 Hold the autoinjector in place until you hear a **second click**. This may take up to 10 seconds. (see **Figure O**).



6.8 Wait and slowly count to 5 after you hear the second click. Continue to hold the autoinjector in place to make sure you inject a full dose (see **Figure P**). **Do not** lift the autoinjector until you are sure 5 seconds has passed, and the injection is complete.



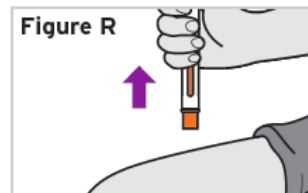
6.9 While holding the autoinjector in place, check the window to make sure the orange plunger rod has fully appeared in the viewing window, and has stopped moving (see **Figure Q**).



Step 7

Remove and check the autoinjector

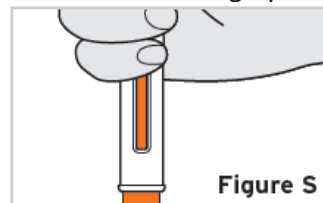
7.1 When the injection is complete, lift the autoinjector straight away from your skin (see **Figure R**).



Note: The needle cover will slide down and cover the needle.

Do not recap the autoinjector.

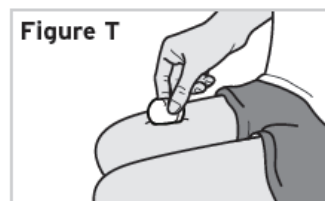
7.2 Check the window to make sure the orange plunger rod came all the way down (see **Figure S**).



Note: If the orange plunger rod did not come all the way down or you believe you did not get a full injection, call your healthcare provider.

Do not try to repeat the injection with a new autoinjector.

7.3 If you see blood on the injection site, press gauze or a cotton ball against on the skin until the bleeding stops (see **Figure T**).

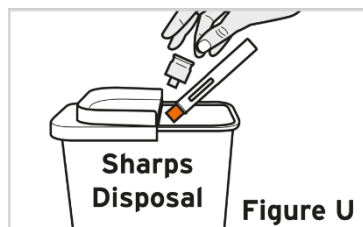


Do not rub the injection site.

Step 8

Throw away your autoinjector

8.1 Put your used autoinjector in an FDA-cleared sharps disposal container right away after use (see **Figure U**).



Do not throw away (dispose of) your autoinjector in your household trash.

If you **do not** have a FDA-cleared sharps disposal container, you can 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.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at <http://www.fda.gov/safesharpsdisposal>

Do not throw away (dispose of) your used sharps disposal container in your household trash unless your community guidelines permit this.

Do not recycle your used sharps disposal container.

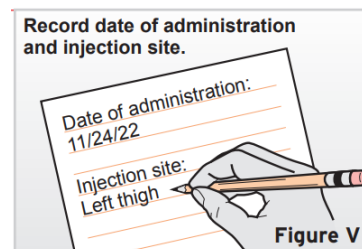
Always keep the sharps disposal container out of reach of children.

Step 9

Record date of administration and injection site

9.1 Write the date, time, and specific part of your body where you injected yourself (see **Figure V**).

It may also be helpful to write any questions or concerns about the injection, so you can ask your healthcare provider.



Manufactured by:
Fresenius Kabi USA, LLC
Lake Zurich, Illinois 60047
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This Instructions for Use has been approved by the U.S. Food and Drug Administration

Issued: 3/2024