

Instructions for Use

Tyenne[®]
tocilizumab-aazg

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



Read these instructions carefully
before using your Tyenne prefilled syringe.

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

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

Important Information

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

Using TYENNE prefilled syringe

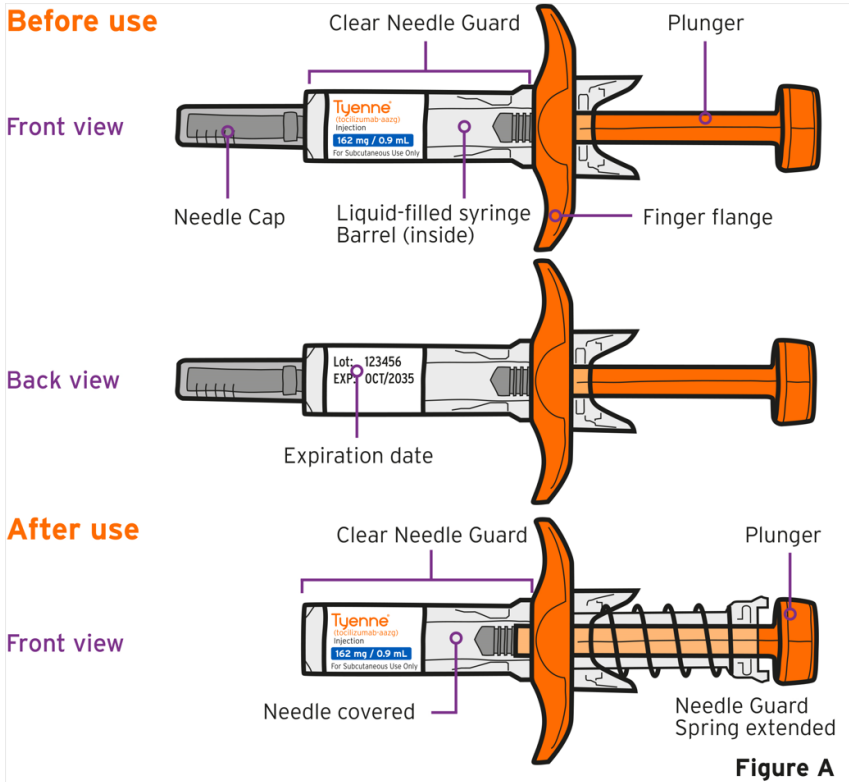
- The prefilled syringe is for self-injection or administration with the help of a caregiver.
- **Do not** use the prefilled syringe if the sealed plastic tray or carton are open or damaged.
- **Do not** use the prefilled syringe if it has been dropped on a hard surface.
The prefilled syringe may be broken even if you cannot see the break.

Storing TYENNE prefilled syringes

- Store TYENNE in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Store unused prefilled syringes in the original carton to protect from light.
- Keep the prefilled syringes out of the reach of children.
- **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.
- If needed, for example when traveling, 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 sharps disposal container if it has been out of the refrigerator for 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.

Your TYENNE prefilled syringe (see Figure A)



Do not try to activate the clear needle guard before injecting.

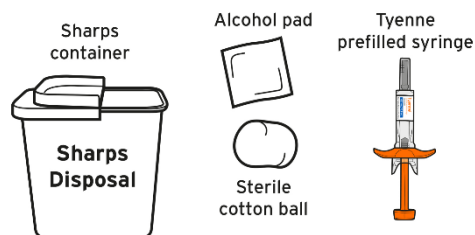
Do not insert your fingers into the opening of the clear needle guard because the needle could injure you.

Step 1 Prepare for your injection

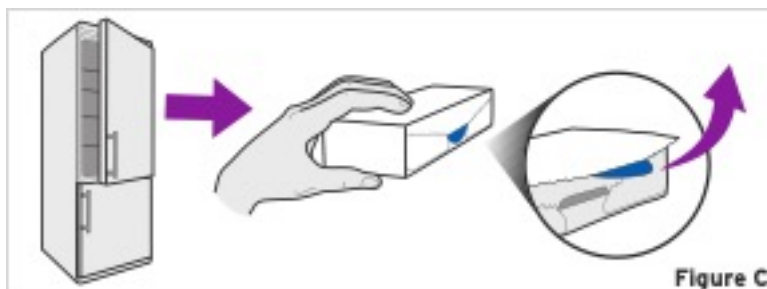
1.1 Find a comfortable space with a clean, flat working surface.

1.2 Supplies needed for your TYENNE prefilled syringe injection (see Figure B):

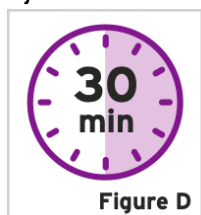
- TYENNE prefilled syringe
- An alcohol pad
- A sterile cotton ball or gauze
- Puncture-resistant container or sharps container for safe disposal of used syringe (see Step 7 “Throw away used prefilled syringe”)



1.3 Take the box containing the syringe out of the refrigerator and open the box (see Figure C).



1.4 Remove the sealed plastic tray out of the box and let it warm up for 30 minutes to reach room temperature (**see Figure D**). 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.

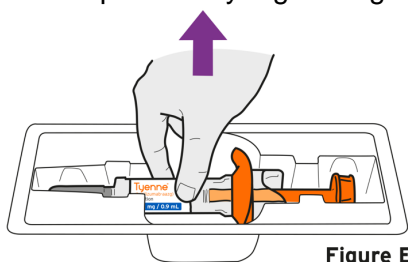


- **Do not** speed up the warming process in any way, such as in a microwave or placing the syringe in hot water.
- Prepare and check your records of previous injection sites. This will help you choose the appropriate injection site for this injection (see **Step 8 “Record your injection”**).

Step 2 Check the syringe

Remove TYENNE prefilled syringe from the sealed plastic tray

- Peel off the seal from the sealed plastic tray.
- Place two fingers on either side, in the middle of the clear needle guard.
- Pull the prefilled syringe straight up and out of the tray (**see Figure E**).

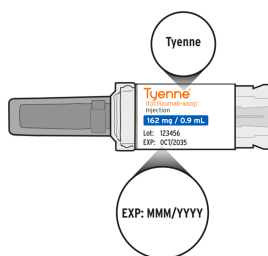


- **Do not** pick up the prefilled syringe by the plunger or the needle cap. Doing so could damage the prefilled syringe or activate the clear needle guard.

2.1 Check the expiration date on the TYENNE prefilled syringe (**see Figure F**).

Do not use it 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.

2.2 Check the name on the prefilled syringe says TYENNE (**see Figure F**).



2.3 Check the liquid in the TYENNE prefilled syringe. It should be clear and colorless to pale yellow (**see Figure G**).

Do not inject TYENNE 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.

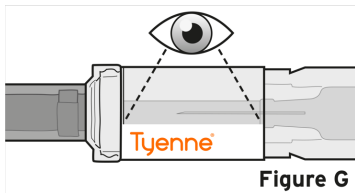


Figure G

2.4 Check the prefilled syringe to make sure that:

- The prefilled syringe, the clear needle guard, and the needle cap are not cracked or damaged (see **Figure H**).
- The needle cap is securely attached (see **Figure I**).
- The needle guard spring is not extended (see **Figure J**).

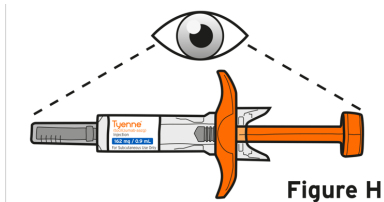


Figure H

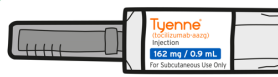


Figure I

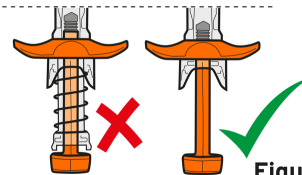


Figure J

- **Do not** use the syringe if it shows any sign of damage. If damaged, call your healthcare provider or pharmacist right away and throw away the syringe in your sharps disposal container (see **Step 7 “Throw away used prefilled syringe”**).

Step 3 Wash your hands

Wash your hands well with soap and water (see **Figure K**).

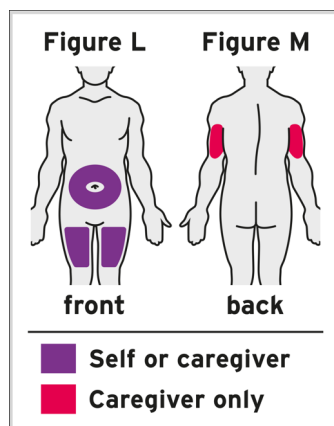


Figure K

Step 4 Choose the injection site

4.1 Choose an injection site

- The front of the thighs and your belly (abdomen) except for 2-inch area around your navel are the recommended injection sites (see **Figure L**).
- 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 M**).



4.2 Rotate injection site

- Choose a different injection site for each new injection.
- **Do not** inject into moles, scars, bruises, or areas where the skin is tender, red, hard or not intact.

Step 5 Clean the injection site

5.1 Clean 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 injection. **Do not** touch the injection site again before giving the injection.
- **Do not** fan or blow on the clean area.

Step 6 Give your injection

6.1 Remove the needle cap.

- Hold the TYENNE prefilled syringe by the clear needle guard with 1 hand and pull the needle cap straight off with your other hand (**see Figure N**).

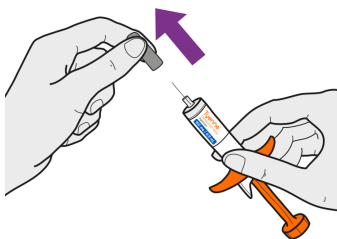


Figure N

- **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.
- Throw away the needle cap in your sharps container.
- There may be a small air bubble in the TYENNE prefilled syringe. You do not need to remove it.
- You may see drops 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.

6.2 Pinch the skin

- Hold the TYENNE prefilled syringe in 1 hand between the thumb and index finger (**see Figure O**).

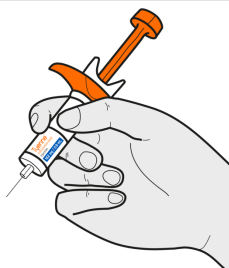


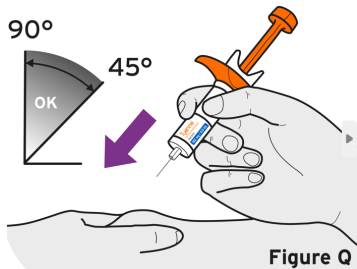
Figure O

- **Do not** pull back on the plunger of the syringe.
- Use your other hand and gently pinch the area of skin firmly (**see Figure P**). 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.



6.3 Insert the needle

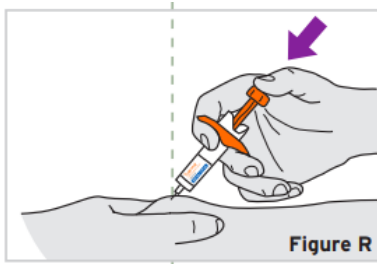
- Use a quick, dart-like motion to insert the needle all the way into the pinched skin at an angle between 45° to 90° (see **Figure Q**). It is important to use the correct angle to make sure the medicine is delivered under the skin (into fatty tissue), or the injection could be painful, and the medicine may not work.



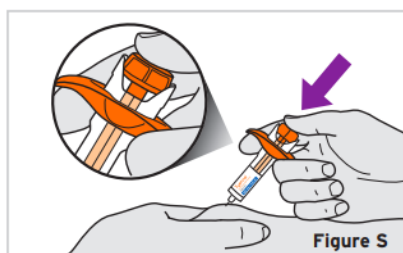
- Keep the syringe in position.
- **Do not** hold or push on the plunger while inserting the needle into the skin.

6.4 Inject

- Slowly inject all of the medicine by gently pushing the plunger all the way down (see **Figure R**).



- You must press the plunger all the way down to get the full dose of medicine until you cannot press any more (see **Figure S**).



- **Do not** pull the needle out of the skin when the plunger is pushed all the way down.

6.5 Finish Injection

- After the plunger is pushed all the way down, hold the syringe firmly without moving it, at the same angle as inserted.
- Slowly release your thumb off the plunger. The plunger will move up. The safety system will remove the needle from the skin and cover the needle (see **Figure T**).

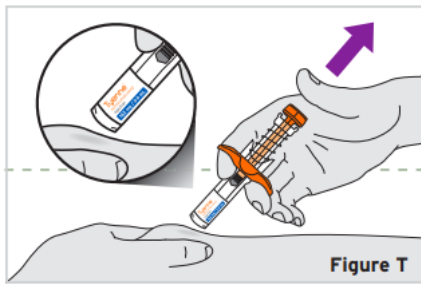


Figure T

- Release the pinched skin

Important: Call your healthcare provider right away if you did not inject the full dose. Injecting an incorrect amount of medicine could affect your treatment.

Do not reuse a syringe even if all of the medicine was not injected.

Do not try to recap the needle as it could lead to needle stick injury.

6.6 After the injection

- There may be a little bleeding at the injection site. You can press a cotton ball or gauze on the injection site.
- **Do not** rub the injection site.
- If needed, you may cover the injection site with a small bandage.

Step 7 → Throw away used prefilled syringe

- The TYENNE prefilled syringe should not be reused.
- **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 syringe and disposing of the syringe to prevent accidental needle stick injury and passing injection.**

How do I throw away used syringes ?

Put your used syringe in an FDA-cleared sharps disposal container right away after use (see Figure U). **Do not throw away (dispose of) loose needles and syringes in your household trash.**

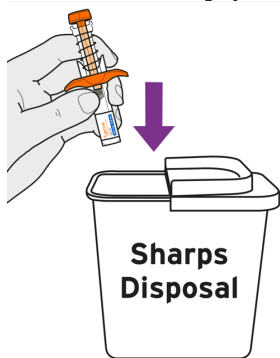


Figure U

- 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

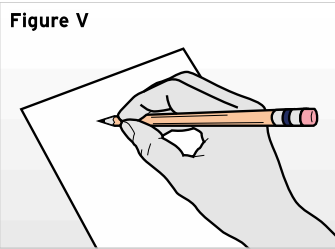
- properly labeled to warn of hazardous waste inside the container.
 - When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state 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.

Keep TYENNE prefilled syringes and disposal container out of the reach of children.

Step 8 Record your injection

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

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

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