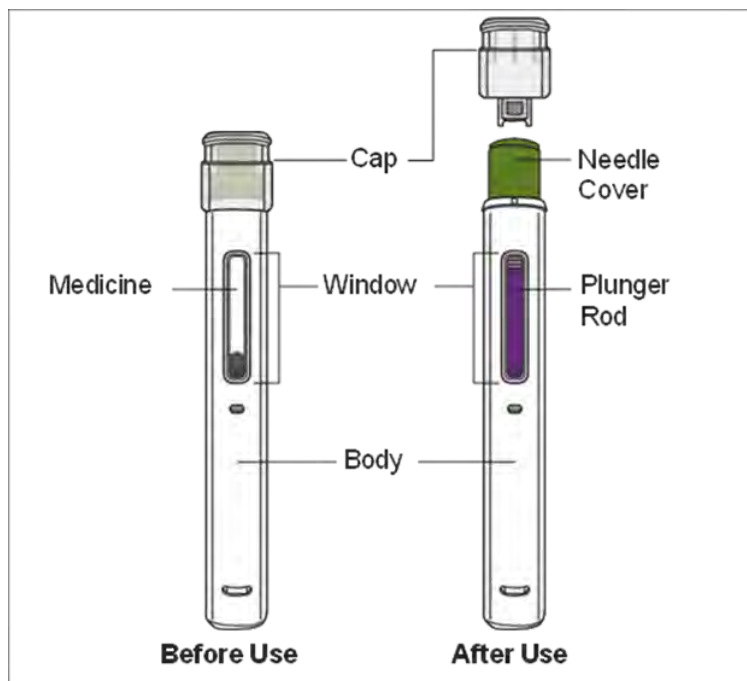


INSTRUCTIONS FOR USE
ZYMFENTRA (Zim fen' trah)
(infliximab-dyyb)
Injection for subcutaneous use only
Single-Dose Prefilled Pen
120 mg/mL
Rx Only

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

Figure A: Parts of ZYMFENTRA Prefilled Pen



Important Information

- Use the Prefilled Pen **only** if your healthcare provider has trained you on the right way to prepare for and to give an injection.
- Ask your healthcare provider how often you will need to give an injection.
- Rotate the injection site each time you give an injection. Each new injection site should be at least 1.2 inches away from the previous injection site.
- **Do not** shake the Prefilled Pen at any time.
- **Do not** remove the Cap until you are ready to inject.
- **Do not** share the Prefilled Pen with anyone.

How to store the Prefilled Pen

- Store the Prefilled Pen in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the Prefilled Pen in the original carton until use to protect it from light.
- **Do not** use the Prefilled Pen that has been left in direct sunlight.
- **Do not** freeze the Prefilled Pen. If the Prefilled Pen has been frozen, **do not** use Prefilled Pen even if it is thawed.
- **Do not** warm the Prefilled Pen using heat sources such as hot water or a microwave. Let the Prefilled Pen naturally warm at room temperature between 68°F to 77°F (20°C to 25°C) for 30 minutes before giving an injection.
- When the Prefilled Pen has reached room temperature, **do not** put it back in the refrigerator.
- **Keep the Prefilled Pen and all medicines out of the reach of children.**

Prepare for the Injection

1. Gather the supplies for the injection.

1a. Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.

1b. Remove 1 Prefilled Pen from the carton stored in your refrigerator.

Note: Return the carton with any unused Prefilled Pens to refrigerator immediately after taking out one Prefilled Pen.

1c. Make sure you have the following supplies:

- Prefilled Pen
- 1 Alcohol swab

Not included in the carton:

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

2. Inspect the Prefilled Pen.

2a. Make sure you have the correct medicine (ZYMFENTRA).

2b. Check the expiration (EXP) date on the label of the Prefilled Pen (See Figure B).

2c. Look at the Prefilled Pen and make sure it is not cracked or damaged.

- **Do not** use the Prefilled Pen if:
 - it is cracked or damaged.
 - the expiration (EXP) date has passed.

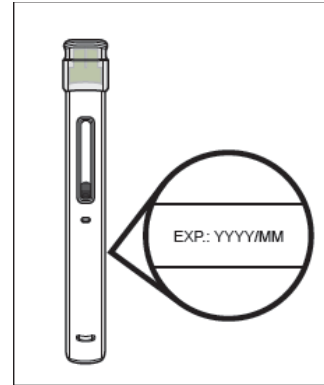


Figure B

3. Inspect the Medicine.

3a. Look through the Window and make sure that the liquid is clear, colorless to pale brown, and free of particles (see Figure C).

- **Do not** use the Prefilled Pen if the liquid is the discolored (yellow or dark brown), cloudy, or contains particles in it.
- You may see air bubbles in the liquid. This is normal.

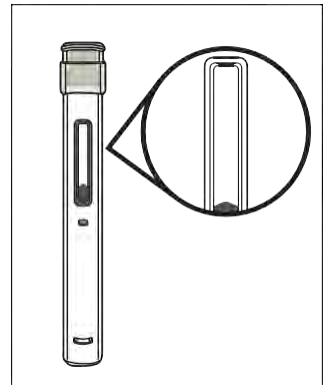


Figure C

4. Wait 30 minutes.

4a. Leave the Prefilled Pen at room temperature 68°F to 77°F (20°C to 25°C) for 30 minutes to allow it to warm up (see Figure D).

- **Do not** warm the Prefilled Pen using heat sources such as hot water or a microwave.

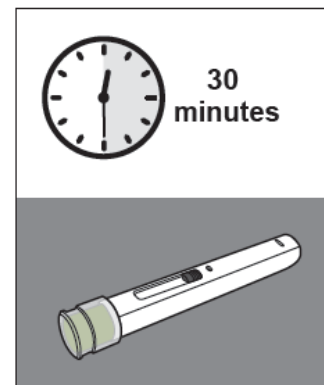


Figure D

5. Choose an injection site (see Figure E).

5a. You may inject into:

- the front of your thighs.
- the stomach area (abdomen) except for the 2 inches around the belly button (navel).
- the outer area of the upper arm if you are a caregiver.
- **Do not** inject into skin that is within 2 inches of your belly button (navel), or is red, hard, tender, damaged, bruised, or scarred.
- **Do not** inject through your clothes.

5b. **Rotate the injection site** each time you give an injection.

- **Do not** inject the same injection site each time you give an injection.
- Each new injection site should be at least 1.2 inches away from the injection site you used before.



Figure E

6. Wash your hands.

6a. Wash your hands with soap and water and dry them thoroughly (see Figure F).

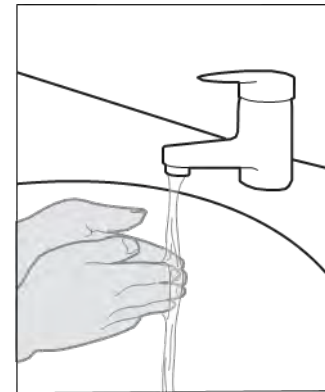


Figure F

7. Clean the injection site.

7a. Clean the injection site with an alcohol swab using a circular motion (see Figure G).

7b. Let the skin dry before injecting.

- **Do not** blow on or touch the injection site again before giving the injection.



Figure G

Give the Injection

8. Remove the Cap.

8a. Hold the Prefilled Pen by the injector body with the Cap on top using one hand. Gently pull the Cap straight off with the other hand.

- **Do not** recap the Prefilled Pen.
- **Do not** remove the Cap until you are ready to inject.
- **Do not** touch the Needle or Needle Cover. Doing so may result in a needle stick injury.

8b. Throw away (dispose of) the Cap in an FDA cleared sharps container (see Step 12 and Figure H).

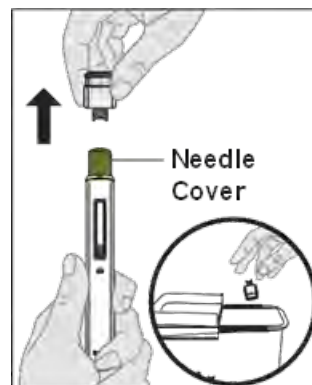


Figure H

9. Place the Prefilled Pen on the injection site.

9a. Hold the Prefilled Pen so that you can see the Window.

9b. Without pinching or stretching the skin, place the Prefilled Pen over the injection site at a 90-degree angle (see Figure I).

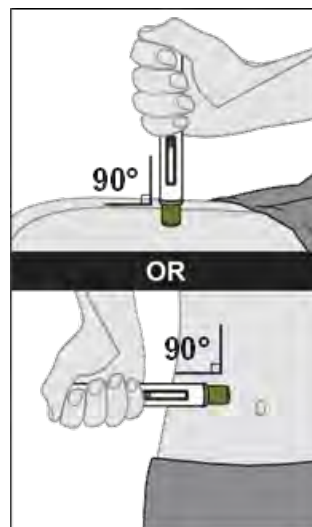


Figure I

10. Give the injection (see Figure J).

10a. Press the Prefilled Pen **firmly** against the skin.

- When the injection starts you will hear the first loud “click” and the purple Plunger Rod will begin to fill the Window.

10b. Keep holding the Prefilled Pen **firmly** against the skin and listen for the second loud “click.” This can take up to 10 seconds.

- **Do not** change the position of the Prefilled Pen after the injection has started.

10c. After you hear the second loud “click” continue to hold the Prefilled Pen **firmly** against the skin and **count slowly to 5** to make sure you inject the full dose.

10d. Look at the Prefilled Pen and make sure that the purple Plunger Rod is filling the Window completely.



Figure J

11. Remove the Prefilled Pen from your skin.

11a. Remove the Prefilled Pen from your skin (see Figure K).

- After you remove the Prefilled Pen from the injection site, the needle will be automatically covered (see Figure L).
- If the Window has not turned completely purple or if the medicine is still injecting, this means you have not received a full dose. Call your healthcare provider immediately.
- You may see grey stopper in the Window. This is normal.
- Some bleeding may occur.
- **Do not** reuse the Prefilled Pen.
- **Do not** rub the injection site.

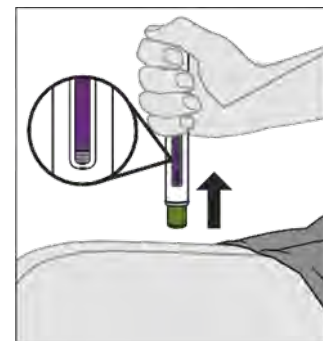


Figure K

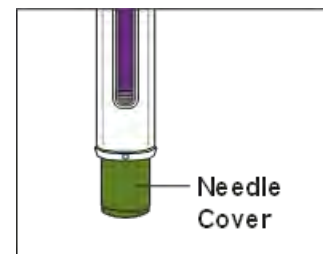


Figure L

After the Injection

12. Throw away (dispose of) the Prefilled Pen.

12a. Put the used Prefilled Pen in an FDA-cleared sharps disposal container right away after use (see Figure M).

- **Do not** throw away (dispose of) the Prefilled Pen 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.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of it. There may be state or local laws about how you should throw away used needles and pens. 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** 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.

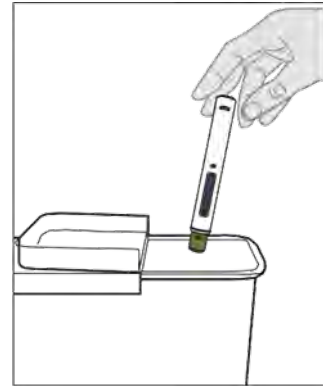


Figure M

13. Care for the injection site.

13a. Treat the injection site by gently pressing, not rubbing, a cotton ball or gauze to the site and apply an adhesive bandage, if necessary.

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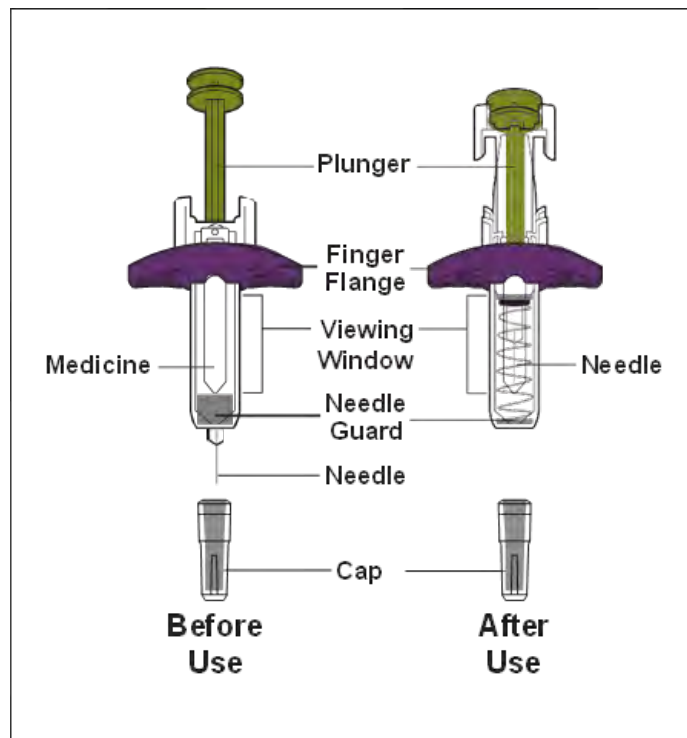
This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Approved: 10/2023

INSTRUCTIONS FOR USE
ZYMFENTRA (Zim fen' trah)
(infliximab-dyyb)
Injection for subcutaneous use only
Single-Dose Prefilled Syringe with Needle Shield
120 mg/mL
Rx Only

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

Figure A: Parts of the Prefilled Syringe



Caution! Do not remove the Cap until you are ready to inject. When you remove the Cap, do not recap the Prefilled Syringe.

Important Information

- Use the Prefilled Syringe **only** if your healthcare provider has trained you on the right way to prepare for and to give an injection.
- Ask your healthcare provider how often you will need to give an injection.
- Rotate the injection site each time you give an injection. Each new injection

- site should be at least 1.2 inches away from the previous injection site.
- **Do not** use the Prefilled Syringe if it has been dropped or is visibly damaged.
- **Do not** reuse the Prefilled Syringe.
- **Do not** shake the Prefilled Syringe at any time.
- **Do not** share the Prefilled Syringe with anyone.
- **Do not** pull back on the plunger rod at any time.
- Only use each Prefilled Syringe for one injection.

How to store the Prefilled Syringe

- Store the Prefilled Syringe in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the Prefilled Syringe in the original carton to protect it from light.
- **Do not** use the Prefilled Syringe that has been left in direct sunlight.
- **Do not** freeze the Prefilled Syringe. If the Prefilled Syringe has been frozen, **do not** use Prefilled Syringe even if it is thawed.
- **Do not** warm the Prefilled Syringe using heat sources such as hot water or a microwave. Let the Prefilled Syringe naturally warm at room temperature between 68°F to 77°F (20°C to 25°C) for 30 minutes before giving an injection.
- When the Prefilled Syringe has reached room temperature, **do not** put it back in the refrigerator.
- **Keep the Prefilled Syringe and all medicines out of the reach of children.**

Prepare for the Injection

1. Gather the supplies for the injection.

1a. Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.

1b. Remove 1 Prefilled Syringe from the carton by holding the middle of the Prefilled Syringe Body.

- **Do not** touch the plunger rod.

Note: Return the carton with any unused Prefilled Syringe to the refrigerator immediately after taking out one Prefilled Syringe.

1c. Make sure you have the following supplies:

- Prefilled Syringe
- Alcohol swab

Not included in the carton:

- Cotton ball or gauze
- Adhesive bandage

- FDA-cleared sharps disposal container

2. Inspect the Prefilled Syringe.

2a. Make sure you have the correct medicines (ZYMFENTRA).

2b. Check the expiration (EXP) date on the label of the Prefilled Syringe (See Figure B).

2c. Look at the Prefilled Syringe and make sure it is not cracked or damaged.

- **Do not** use the Prefilled Syringe if:
 - it is cracked or damaged.
 - the expiration (EXP) date has passed.

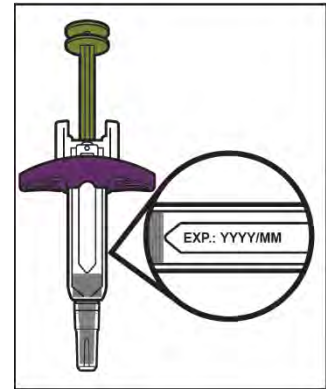


Figure B

3. Inspect the Medicine.

3a. Look through the Viewing Window and check that the liquid is clear, colorless to pale brown, and free of particles (see Figure C).

- **Do not** use the Prefilled Syringe if the liquid is the wrong color, cloudy, or contains particles in it.
- You may see air bubbles in the liquid. This is normal.

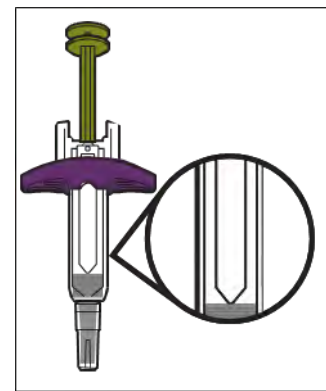


Figure C

4. Wait 30 minutes.

4a. Leave the Prefilled Syringe at room temperature 68°F to 77°F (20°C to 25°C) for 30 minutes to allow it to warm up (see Figure D).

- **Do not** warm the Prefilled Syringe using heat sources such as hot water or a microwave.



Figure D

5. Choose an injection site (see Figure E).

5a. You may inject into:

- the front of your thighs.
- the stomach area (abdomen) except for the 2 inches around the belly button (navel).
- the outer area of the upper arm (**caregiver only**).
- **Do not** inject into skin that is within 2 inches of your belly button (navel), or is tender, damaged, bruised, or scarred.
- **Do not** inject through your clothes.

5b. **Rotate the injection site** each time you give an injection.

- **Do not** injection the same injection site each time you give an injection.
- Each new injection site should be at least 1.2 inches away from the previous injection site.

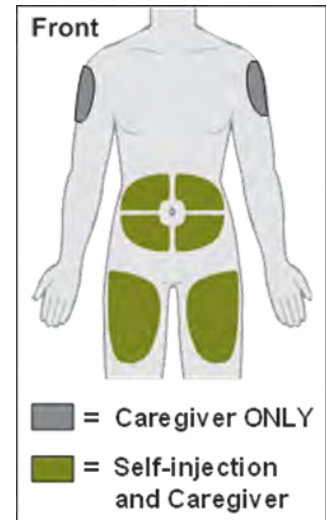


Figure E

6. Wash your hands.

6a. Wash your hands with soap and water and dry them well (see Figure F).



Figure F

7. Clean the injection site.

7a. Clean the injection site with an alcohol swab (see Figure G).

7b. Let the skin dry before injecting.

- **Do not** blow on or touch the injection site again before giving the injection.



Figure G

Give the Injection

8. Remove the Cap.

8a. Hold the Prefilled Syringe by the injector body with the Cap on top using one hand. Gently pull the Cap straight off with the other hand.

- **Do not** pull back on plunger rod at any time.
- **Do not** remove the Cap until you are ready to inject.
- **Do not** try to put the Cap back onto the Prefilled Syringe.
- **Do not** touch the Needle.

8b. Throw away (dispose of) the Cap in an FDA cleared sharps container (see Step 12 and Figure H).

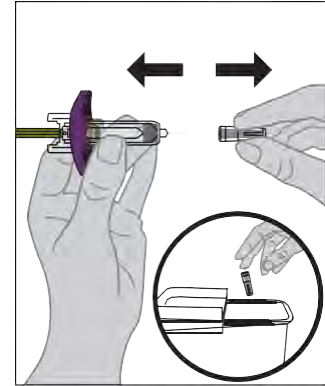


Figure H

9. Insert the Prefilled Syringe into the injection site.

9a. Hold the Prefilled Syringe by its body in one hand between your thumb and index finger.

9b. Gently pinch a fold of skin at the injection site with one hand.

9c. With a quick and “dart-like” motion, insert the Needle completely into the fold of the skin at a 45-degree angle (see Figure I).

- **Do not** change the position of the Prefilled syringe after the injection has started.



Figure I

10. Give the injection.

10a. After the Needle is inserted, release the pinched skin.

10b. Push the Plunger down slowly and as far as it will go until the Prefilled Syringe is empty (See Figure J)

Note: The Needle Guard will not activate unless all the Medicine is injected.

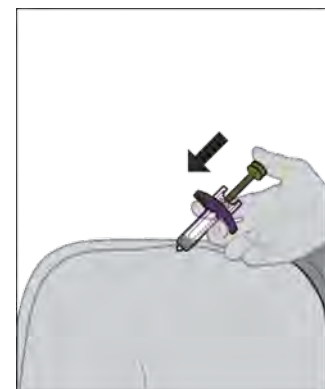


Figure J

11. Remove the Prefilled Syringe from the injection site.

11a. After the Prefilled Syringe is empty, slowly lift your thumb from the Plunger until Needle is completely covered by the Needle guard (see Figure K).

- **Do not** re-use the Prefilled Syringe.
- **Do not** touch the Needle.
- Some bleeding may occur.
- **Do not** rub the injection site.

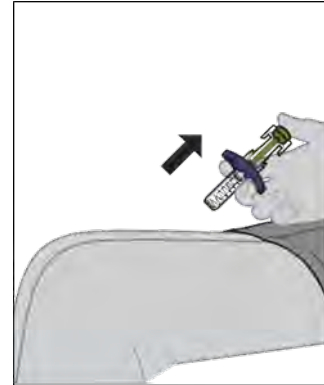


Figure K

After the Injection

12. Throw away (dispose of) the Prefilled Syringe.

12a. Put the used Prefilled Syringe in an FDA-cleared sharps disposal container right after use (see Figure L).

- **Do not** try to put the Cap back on the Prefilled Syringe.
- **Do not** throw away (dispose of) the Prefilled 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,
 - able to close 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 it. 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** 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.



Figure L

13. Care for the injection site.

13a. Treat the injection site by gently pressing a cotton ball or gauze to the site and apply an adhesive bandage, if necessary.

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