

INSTRUCTIONS FOR USE:

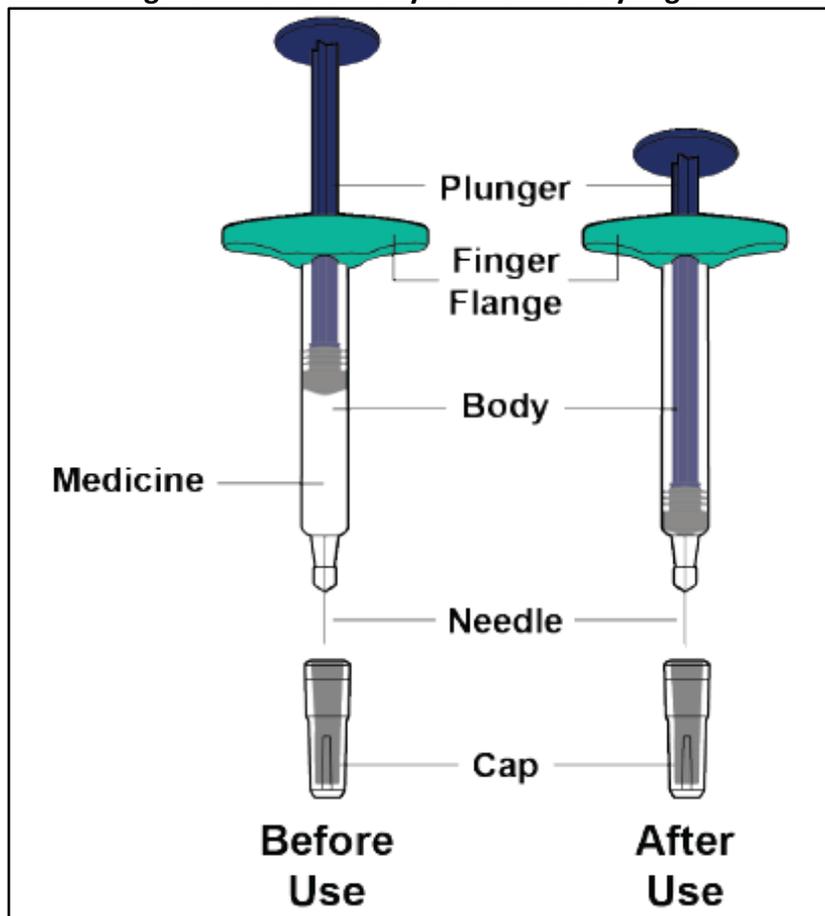
The following instructions are for preparing and giving a dose of Yuflyma™ using a single-use pre-filled syringe, a single-use pre-filled syringe with safety guard, and a single-use auto-injector.

INSTRUCTIONS FOR USE
YUFLYMA™ (yoo-fly'-mah)
(adalimumab injection)
40 mg/0.4 mL
Single-Dose Pre-filled Syringe

For subcutaneous use only

Read and follow the Instructions for Use that come with your Yuflyma Pre-filled 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 Yuflyma Pre-filled Syringe



Important Information

- Use the Pre-filled 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.

- **Do not** shake the Pre-filled Syringe at any time.
- **Do not** remove the Cap until you are ready to inject.
- **Do not** share the Pre-filled Syringe with anyone.
- **Do not** pull back on the plunger rod at any time.

How to store the Pre-filled Syringe

- Store the Pre-filled Syringe in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the Pre-filled Syringe in the original carton to protect it from light.
- **Do not** use a Pre-filled Syringe that has been left in direct sunlight.
- **Do not** freeze the Pre-filled Syringe. If the Pre-filled Syringe has been frozen, **do not** use the Pre-filled Syringe even if it is thawed.
- If needed, you may store the Pre-filled Syringe at room temperature up to 77°F (25°C) for up to 30 days.
- After the Pre-filled Syringe has reached room temperature, **do not** put it back in the refrigerator.
- **Keep the Pre-filled Syringe and all medicines out of the reach of children.**

Read Instructions on All Pages Before Using the Yuflyma Pre-filled Syringe

PREPARE FOR THE INJECTION

1. Gather the supplies for the injection.

- a. Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- b. Remove 1 Pre-filled Syringe from the carton stored in your refrigerator.
 - Hold the Pre-filled Syringe body when removing it from the carton.
Do not touch the plunger rod.
- c. Make sure you have the following supplies:
 - Pre-filled Syringe
 - 1 Alcohol swab

Not included in the carton:

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

2. Inspect the Pre-filled Syringe.

- a. Ensure you have the correct medicine (Yuflyma) and dosage.
- b. Look at the Pre-filled Syringe and make sure it is not cracked or damaged.
- c. Check the expiration date on the label of the Pre-filled Syringe (see **Figure B**)
 - **Do not** use the Pre-filled Syringe if;
 - it is cracked or damaged.
 - the expiration date has passed.

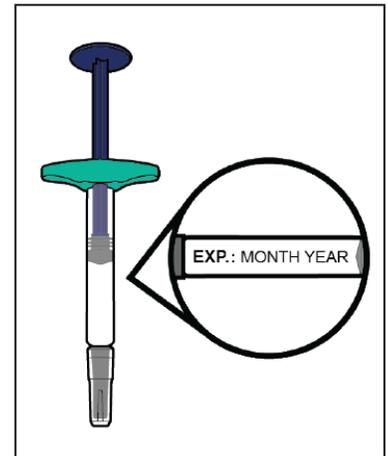


Figure B

3. Inspect the Medicine.

- a. Look at the Medicine and confirm that the liquid is clear, colorless to pale brown, and free of particles (see **Figure C**).
 - **Do not** use the Pre-filled Syringe, 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.

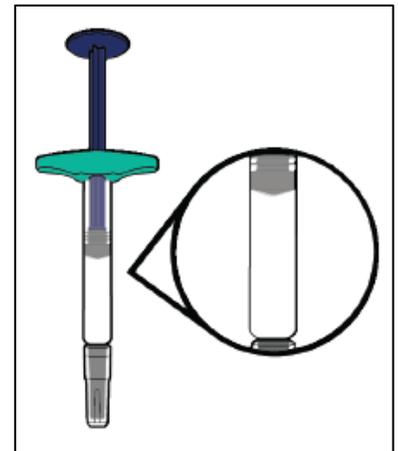


Figure C

4. Wait 15 to 30 minutes.

- a. Leave the Pre-filled 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 (see **Figure D**).
 - **Do not** warm the Pre-filled Syringe using heat sources such as hot water or a microwave.

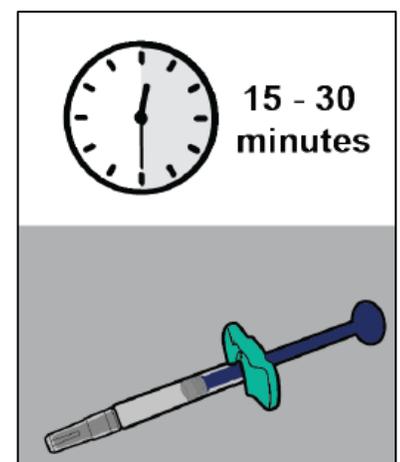


Figure D

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

- a. You may inject into:
 - the front of your thighs.
 - your abdomen except for the 2 in (5 cm) 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 in (5 cm) of your belly button (navel), or is red, hard, tender, damaged, bruised, or scarred.
- If you have psoriasis, **do not** inject directly into any raised, thick, red or scaly skin patches or lesions on your skin.
- **Do not** inject through your clothes.
- b. 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 injection site you used before.

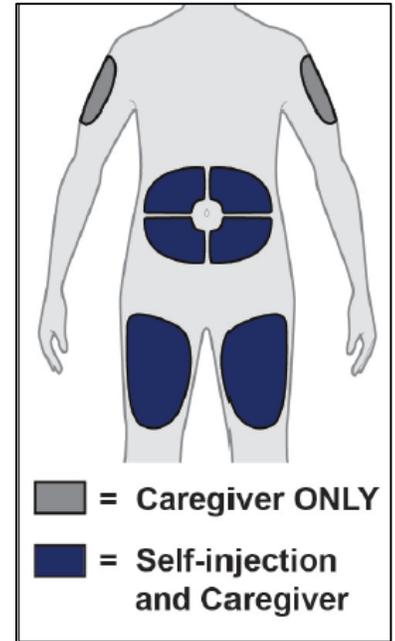


Figure E

6. Wash your hands.

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

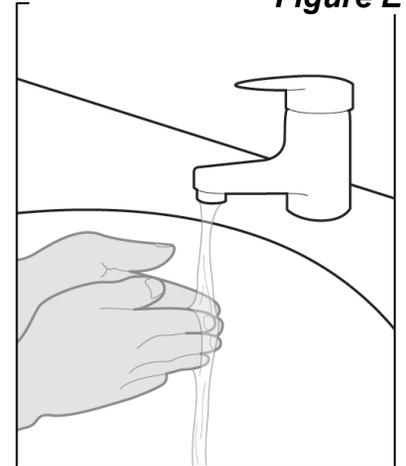


Figure F

7. Clean the injection site.

- a. Clean the injection site with an alcohol swab using a circular motion (see **Figure G**).
- b. Let the skin dry before injecting.
 - **Do not** blow on or touch the injection site again before giving the injection.

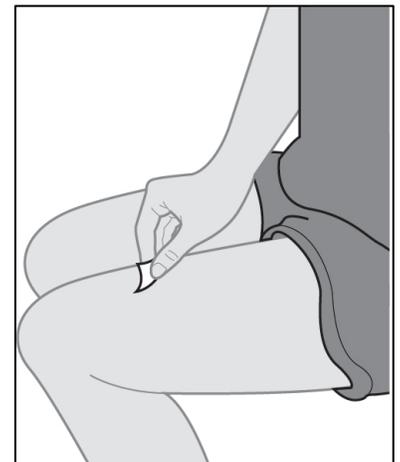


Figure G

GIVE THE INJECTION

8. Remove the Cap.

- a. Hold the Pre-filled Syringe by the injector body with the Cap on top using one hand. Gently pull the Cap straight off with the other hand. Dispose of the Cap in a sharps container (see Step 12 and **Figure H**).
 - **Do not** pull back on the plunger rod at any time.
 - **Do not** recap the Pre-filled Syringe.
 - **Do not** remove the Cap until you are ready to inject.
 - **Do not** touch the Needle. Doing so may result in a needle stick injury.

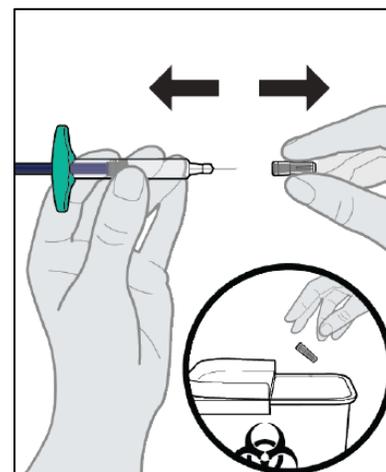


Figure H

9. Insert the Pre-filled Syringe into the injection site.

- a. Gently pinch a fold of skin at the injection site with one hand.
- b. 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**).

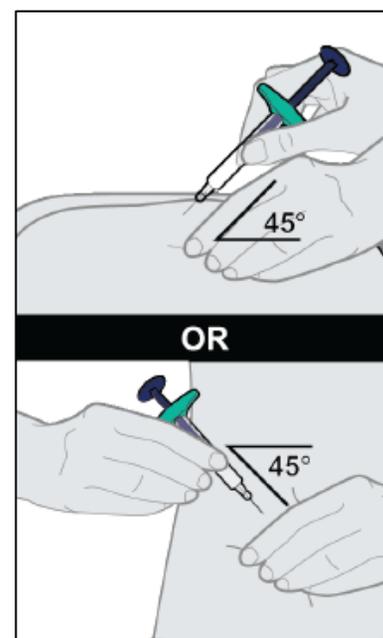


Figure I

10. Give the injection.

- a. After the Needle is inserted, release the pinch.
- b. Slowly push the Plunger all the way down until all of the liquid is injected and the Syringe is empty (see **Figure J**).
 - **Do not** change the position of the Pre-filled Syringe after the injection has started.

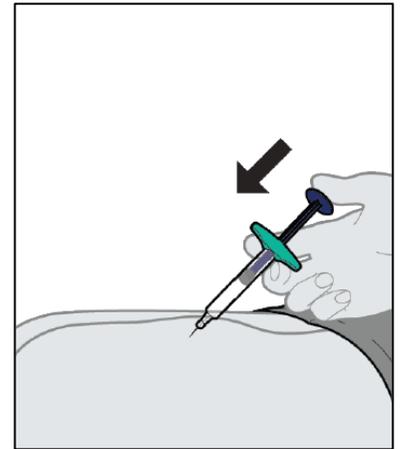


Figure J

11. Remove the Pre-filled Syringe from the injection site.

- a. After the Pre-filled Syringe is empty, remove the Pre-filled Syringe from your skin (see **Figure K**).
 - Some bleeding may occur.
 - **Do not** reuse the Pre-filled Syringe.
 - **Do not** touch the Needle.
 - **Do not** rub the injection site.

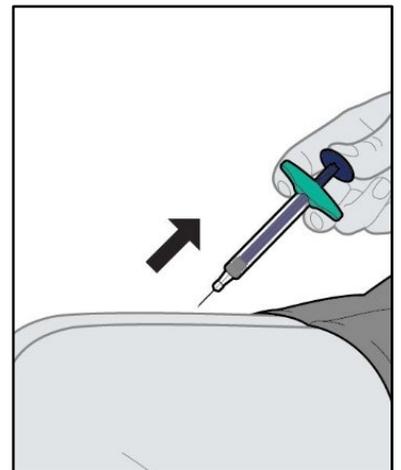


Figure K

AFTER THE INJECTION

12. Dispose of the Pre-filled Syringe.

- a. Put the used Pre-filled Syringe in a sharps disposal container right away after use (see **Figure L**).
 - **Do not** throw away (dispose of) the Pre-filled Syringe in your household trash.
 - If you do not have an 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 syringes.
 - **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.

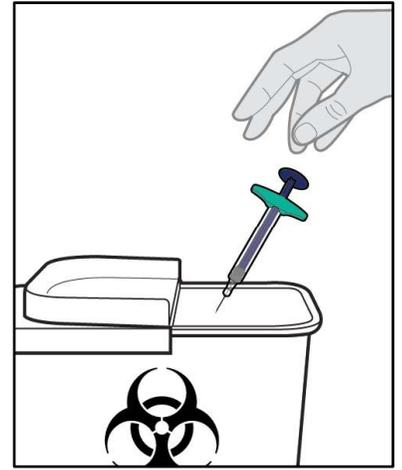


Figure L

13. Care for the injection site.

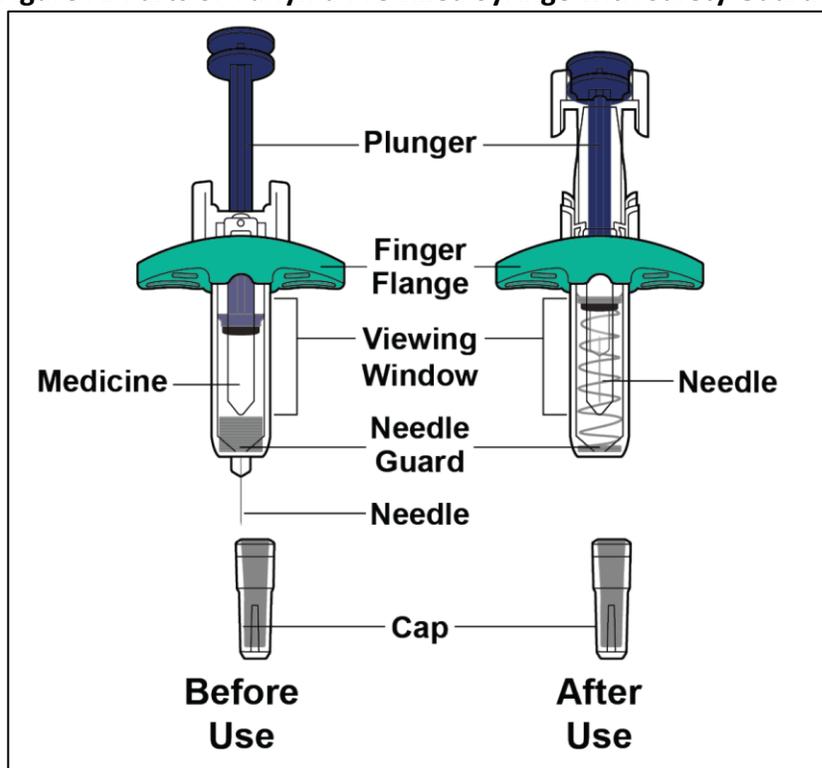
- a. Treat the injection site by gently pressing, not rubbing, a cotton ball or gauze to the site and apply an adhesive bandage, if necessary.

INSTRUCTIONS FOR USE
YUFLYMA™ (yoo-fly'-mah)
(adalimumab injection)
40 mg/0.4 mL
Single-Dose Pre-filled Syringe with Safety Guard

For subcutaneous use only

Read and follow the Instructions for Use that come with your Yuflyma Pre-filled Syringe with Safety Guard 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 Yuflyma Pre-filled Syringe with Safety Guard



Important Information

- Use the Pre-filled Syringe with Safety Guard **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.
- **Do not** shake the Pre-filled Syringe at any time.
- **Do not** remove the Cap until you are ready to inject.
- **Do not** share the Pre-filled Syringe with anyone.

- Only use each Pre-filled Syringe for one injection.
- Do not pull back on the plunger rod at any time.

How to store the Pre-filled Syringe

- Store the Pre-filled Syringe in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the Pre-filled Syringe in the original carton to protect it from light.
- **Do not** use a Pre-filled Syringe that has been left in direct sunlight.
- **Do not** freeze the Pre-filled Syringe. If the Pre-filled Syringe has been frozen, **do not** use the Pre-filled Syringe even if it is thawed.
- If needed, you may store the Pre-filled Syringe at room temperature up to 77°F (25°C) for up to 30 days.
- After the Pre-filled Syringe has reached room temperature, **do not** put it back in the refrigerator.
- **Keep the Pre-filled Syringe and all medicines out of the reach of children.**

Read Instructions on All Pages Before Using the Yuflyma Pre-filled Syringe

PREPARE FOR THE INJECTION

1. Gather the supplies for the injection.

- a. Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- b. Remove 1 Pre-filled Syringe from the carton stored in your refrigerator.
 - Hold the Pre-filled Syringe body when removing it from the carton.
Do not touch the plunger rod.
- c. Make sure you have the following supplies:

- Pre-filled Syringe
- 1 Alcohol swab

Not included in the carton:

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

2. Inspect the Pre-filled Syringe.

- a. Ensure you have the correct medicine (Yuflyma) and dosage.
- b. Look at the Pre-filled Syringe and make sure it is not cracked or damaged.
- c. Check the expiration date on the label of the Pre-filled Syringe (see **Figure B**)
 - **Do not** use the Pre-filled Syringe if;
 - it is cracked or damaged.
 - the expiration date has passed.

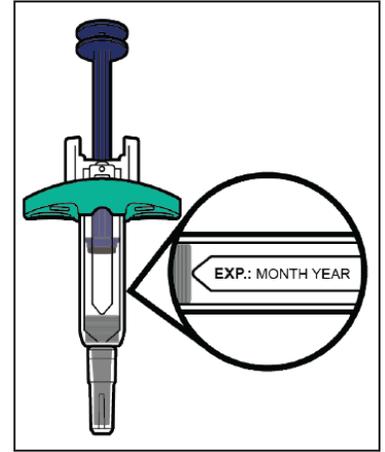


Figure B

3. Inspect the Medicine.

- a. Look at the Medicine and confirm that the liquid is clear, colorless to pale brown, and free of particles (see **Figure C**).
 - **Do not** use the Pre-filled Syringe 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.

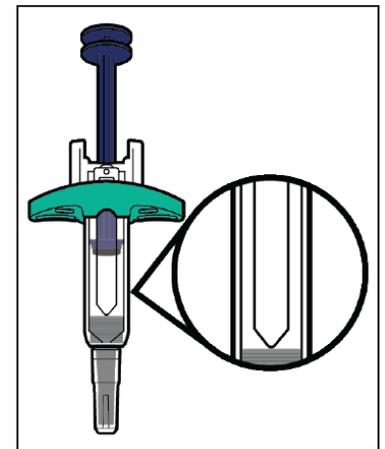


Figure C

4. Wait 15 to 30 minutes.

- a. Leave the Pre-filled 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 (see **Figure D**).
 - **Do not** warm the Pre-filled Syringe using heat sources such as hot water or a microwave.

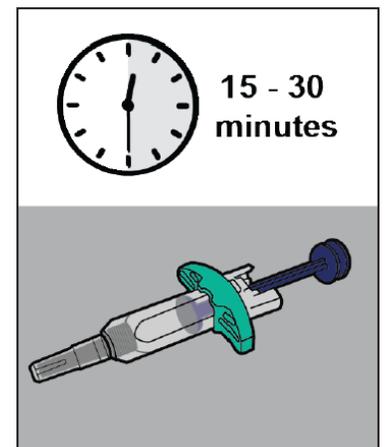


Figure D

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

- a. You may inject into:
- the front of your thighs.
 - your abdomen except for the 2 in (5 cm) 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 in (5 cm) of your belly button (navel), or is red, hard, tender, damaged, bruised, or scarred.
 - If you have psoriasis, **do not** inject directly into any raised, thick, red or scaly skin patches or lesions on your skin.
 - **Do not** inject through your clothes.
- b. 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 injection site you used before.

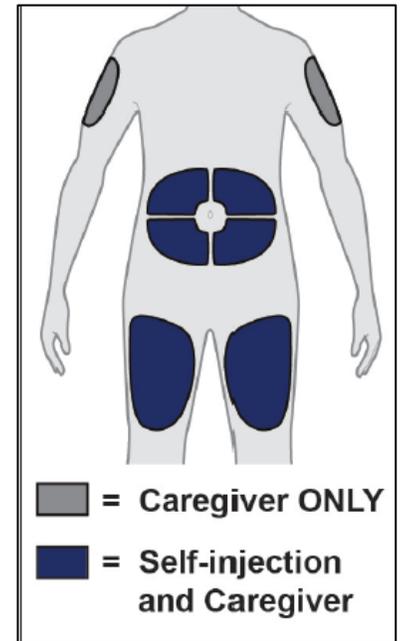


Figure E

6. Wash your hands.

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

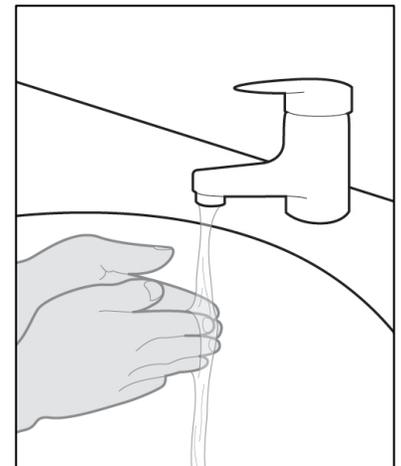


Figure F

7. Clean the injection site.

- a. Clean the injection site with an alcohol swab using a circular motion (see **Figure G**).
- b. Let the skin dry before injecting.
 - **Do not** blow on or touch the injection site again before giving the injection.

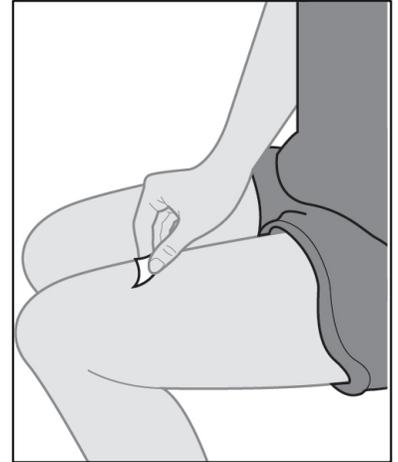


Figure G

GIVE THE INJECTION

8. Remove the Cap.

- a. Hold the Pre-filled Syringe by the injector body with the Cap on top using one hand. Gently pull the Cap straight off with the other hand. Dispose of the Cap in a sharps container (see Step 12 and **Figure H**).
 - **Do not** pull back on the plunger rod at any time.
 - **Do not** recap the Pre-filled Syringe.
 - **Do not** remove the Cap until you are ready to inject.
 - **Do not** touch the Needle. Doing so may result in a needle stick injury.

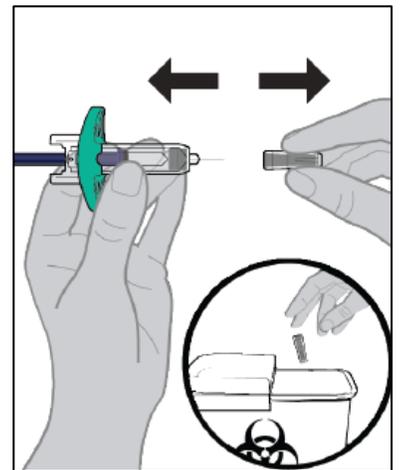


Figure H

9. Insert the Pre-filled Syringe into the injection site.

- a. Gently pinch a fold of skin at the injection site with one hand.
- b. 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**).

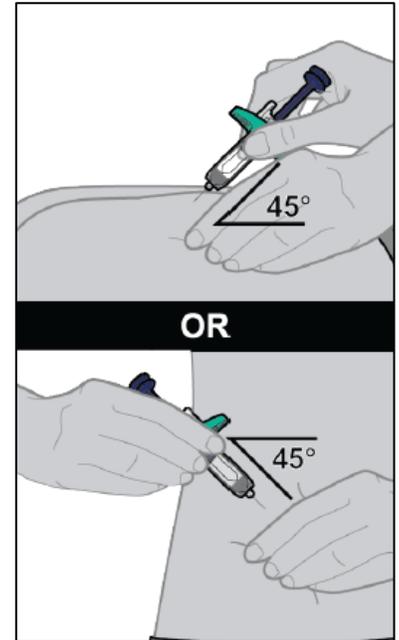


Figure I

10. Give the injection.

- a. After the Needle is inserted, release the pinch.
- b. Slowly push the Plunger all the way down until all of the liquid is injected and the Syringe is empty (see **Figure J**).
 - **Do not** change the position of the Pre-filled Syringe after the injection has started.

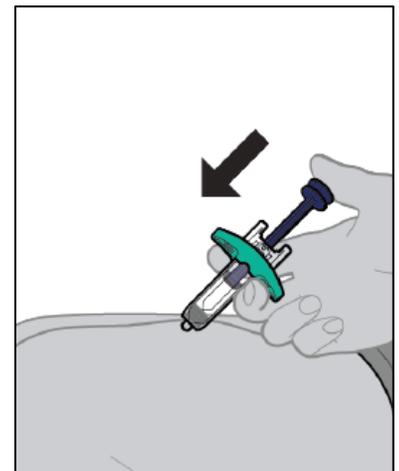


Figure J

11. Remove the Pre-filled Syringe from the injection site.

- a. After the Pre-filled Syringe is empty, slowly lift your thumb from the Plunger until Needle is completely covered by the Safety Guard (see **Figure K**).
 - Some bleeding may occur.
 - **Do not** reuse the Pre-filled Syringe.
 - **Do not** touch or recap the needle.
 - **Do not** rub the injection site.

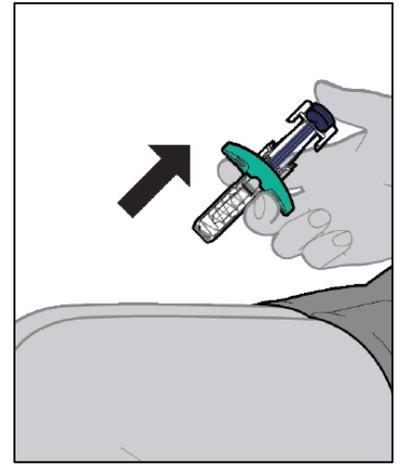


Figure K

AFTER THE INJECTION

12. Dispose of the Pre-filled Syringe.



Figure L

- a. Put the used Pre-filled Syringe in a sharps disposal container right away after use (see **Figure L**).
 - **Do not** throw away (dispose of) the Pre-filled Syringe in your household trash.
 - If you do not have a 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 syringes.
- **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.

13. Care for the injection site.

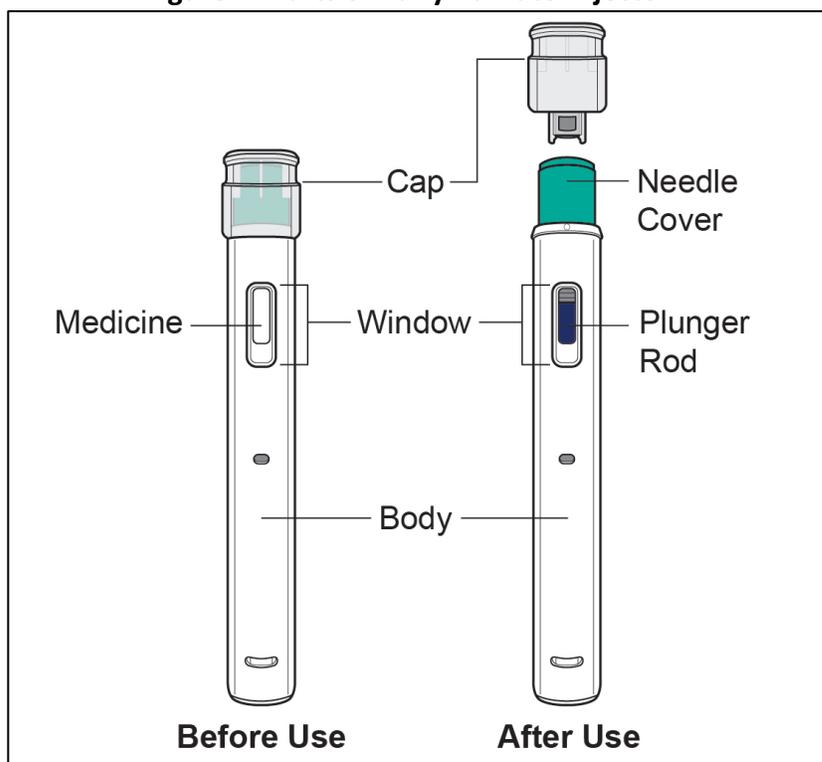
Treat the injection site by gently pressing, not rubbing, a cotton ball or gauze to the site and apply an adhesive bandage, if necessary.

INSTRUCTIONS FOR USE
YUFLYMA™ (yoo-fly'-mah)
(adalimumab injection)
40 mg/0.4 mL
Single-Dose Auto-injector (pre-filled pen)

For subcutaneous use only

Read and follow the Instructions for Use that come with your Yuflyma Auto-injector 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 Yuflyma Auto-injector



Important Information

- Use the Auto-injector **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.
- **Do not** shake the Auto-injector at any time.
- **Do not** remove the Cap until you are ready to inject.
- **Do not** share the Auto-injector with anyone.

How to store the Auto-injector

- Store the Auto-injector in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Keep the Auto-injector in the original carton to protect it from light.
- **Do not** use an Auto-injector that has been left in direct sunlight.
- **Do not** freeze the Auto-injector. If the Auto-injector has been frozen, **do not** use the Auto-injector even if it is thawed.
- If needed, you may store the Auto-injector at room temperature up to 77°F (25°C) for up to 30 days.
- After the Auto-injector has reached room temperature, **do not** put it back in the refrigerator.
- **Keep the Auto-injector and all medicines out of the reach of children.**

Read Instructions on All Pages Before Using the Yuflyma Auto-I

PREPARE FOR THE INJECTION

1. Gather the supplies for the injection.

- a. Prepare a clean, flat surface, such as a table or countertop, in a well-lit area.
- b. Remove 1 Auto-injector from the carton stored in your refrigerator.
- c. Make sure you have the following supplies:

- Auto-injector
- 1 Alcohol swab

Not included in the carton:

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

2. Inspect the Auto-injector.

- a. Ensure you have the correct medicine (Yuflyma) and dosage.
- b. Look at the Auto-injector and make sure it is not cracked or damaged.
- c. Check the expiration date on the label of the Auto-injector (see *Figure B*)
 - **Do not** use the Auto-injector if;
 - it is cracked or damaged.
 - the expiration date has passed.

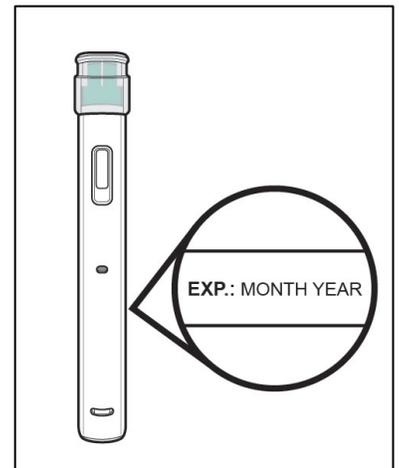


Figure B

3. Inspect the Medicine.

- a. 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 Auto-injector 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.

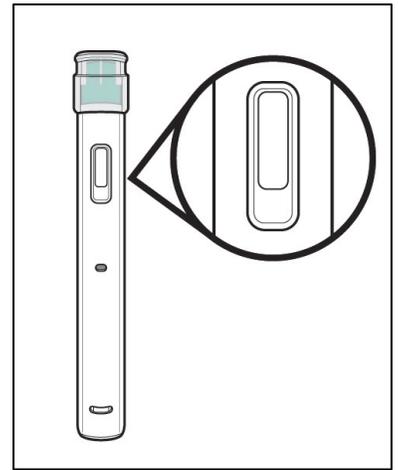


Figure C

4. Wait 15 to 30 minutes.

- a. Leave the Auto-injector at room temperature 68°F to 77°F (20°C to 25°C) for 15 to 30 minutes to allow it to warm up (see *Figure D*).
 - **Do not** warm the Auto-injector using heat sources such as hot water or a microwave.

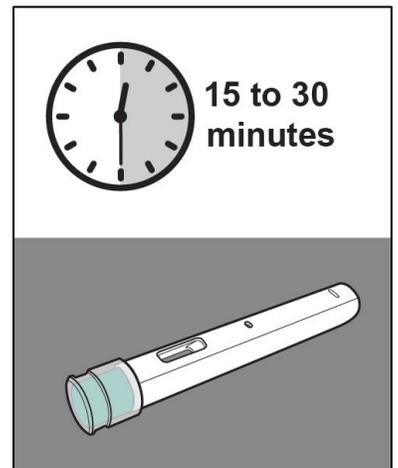


Figure D

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

- c. You may inject into:
- the front of your thighs.
 - your abdomen except for the 2 in (5 cm) 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 in (5 cm) of your belly button (navel), or is red, hard, tender, damaged, bruised, or scarred.
 - If you have psoriasis, **do not** inject directly into any raised, thick, red or scaly skin patches or lesions on your skin.
 - **Do not** inject through your clothes.
- d. 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 injection site you used before.

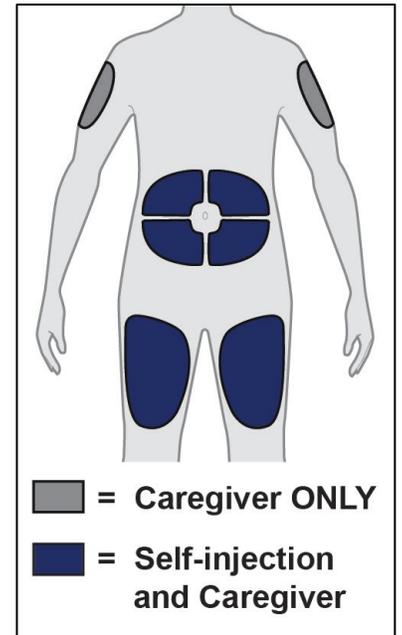


Figure E

6. Wash your hands.

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

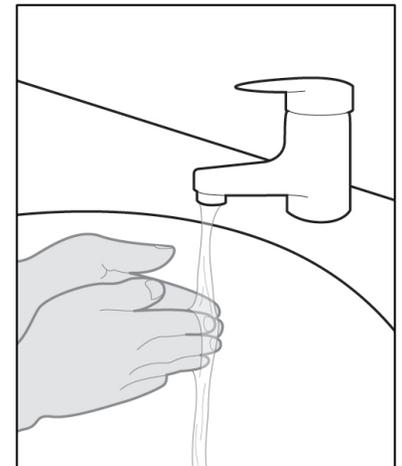


Figure F

7. Clean the injection site.

- a. Clean the injection site with an alcohol swab using a circular motion (see **Figure G**).
- b. Let the skin dry before injecting.
 - **Do not** blow on or touch the injection site again before giving the injection.

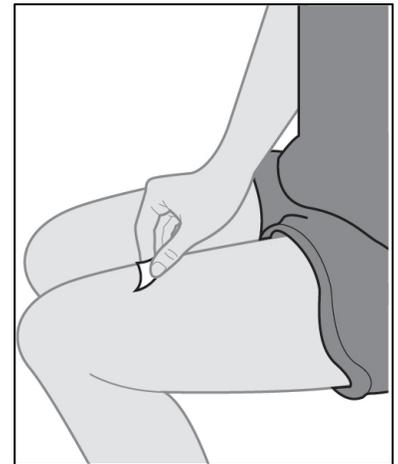


Figure G

GIVE THE INJECTION

8. Remove the Cap.

- a. Hold the Auto-injector by the injector body with the Cap on top using one hand. Gently pull the Cap straight off with the other hand. Dispose of the Cap in a sharps container (see **Step 12** and **Figure H**).
 - **Do not** recap the Auto-injector.
 - **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.

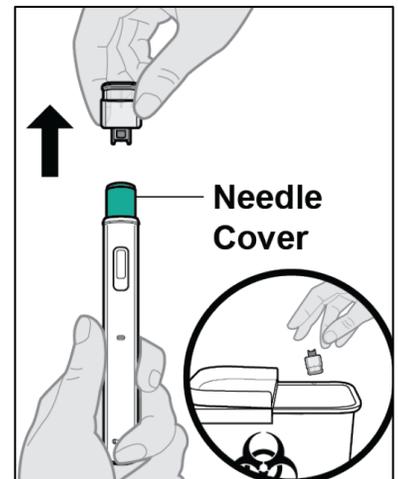


Figure H

9. Place the Auto-injector on the injection site.

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

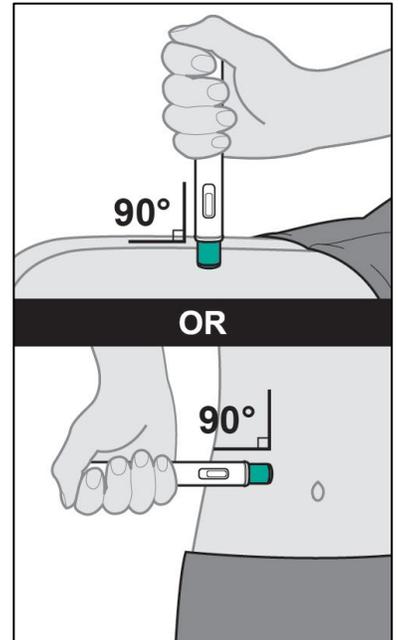


Figure I

10. Give the injection (see *Figure J*).

- a. 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.
- b. Keep holding the Auto-injector **firmly** against the skin and listen for the 2nd loud “click.”
 - **Do not** change the position of the Auto-injector after the injection has started.
- c. After you hear the 2nd loud “click” continue to hold the Auto-injector **firmly** against the skin and **count slowly to 5** to make sure you inject the full dose.

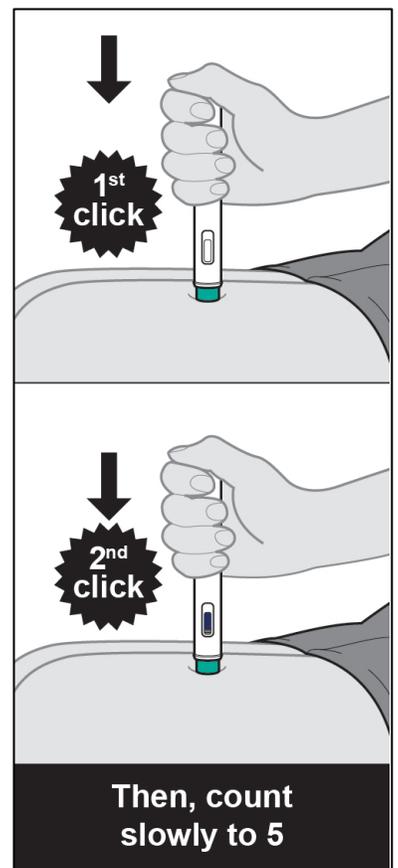


Figure J

11. Remove the Auto-injector from the injection site.

- a. Look at the Auto-injector and make sure that the blue Plunger Rod is filling the Window completely
- b. Remove the Auto-injector from your skin (*see Figure K*).
 - After you remove the Auto-injector from the injection site, the needle will be automatically covered (see *Figure L*).
 - If the Window has not turned completely blue or if the medicine is still injecting, this means you have not received a full dose. Call your healthcare provider immediately.
 - Some bleeding may occur.
 - **Do not** reuse the Auto-injector.
 - **Do not** rub the injection site.

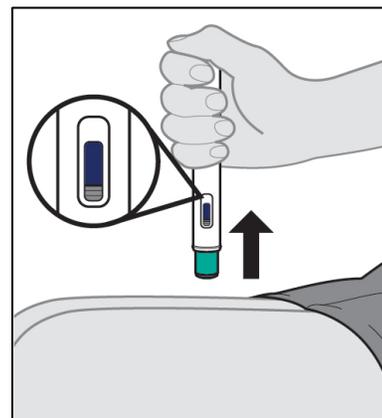


Figure K

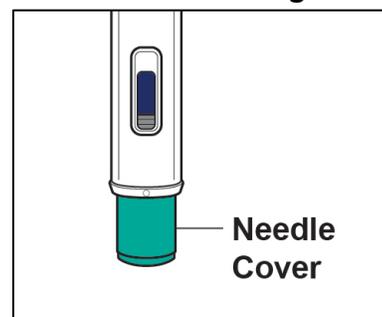


Figure L

AFTER THE INJECTION

12. Dispose of the Auto-injector.

- a. Put the used Auto-injector in a sharps disposal container right away after use (*see Figure M*).
 - **Do not** throw away (dispose of) the Auto-injector in your household trash.
 - If you do not have a 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

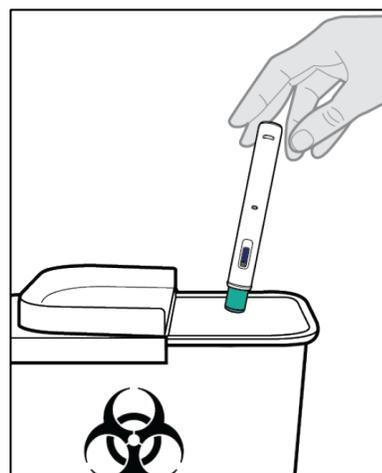


Figure M

- 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.
- **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.

13. Care for the injection site.

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