

7. Instruction For Use

Idacio[®]

Single use pre-filled syringe (adalimumab) for subcutaneous injection 40mg



Note : images for illustration purposes only

Read carefully these entire instructions before using your Idacio pre-filled syringe.

Important Information

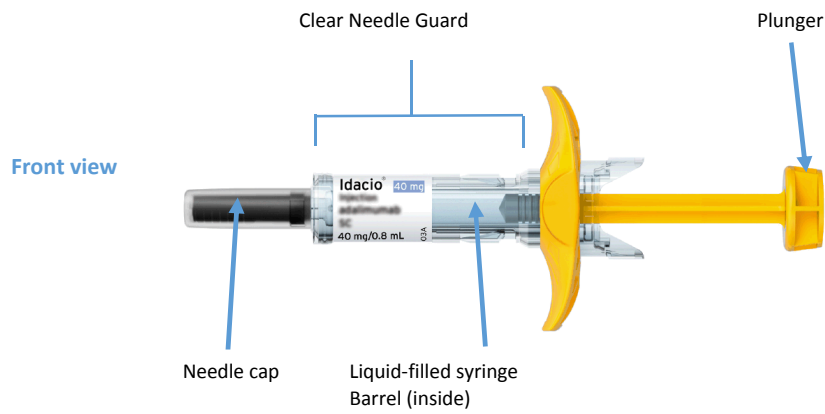
- Only use Idacio pre-filled syringe if your healthcare professional has trained you on how to use the pre-filled syringe correctly.
- Idacio is a pre-filled syringe for single use only.
- Idacio pre-filled syringe has a clear needle guard that covers the needle after the injection is complete.
- Children under 12 years of age are not allowed to inject themselves and injection must be done by a trained adult.
- Keep Idacio pre-filled syringe and the sharps disposal container out of reach and sight of children.
- **Do not** shake. Shaking can damage the pre-filled syringe and the medicine.
- **Do not** use Idacio the pre-filled syringe if liquid appears cloudy or discolored, or has -particles or flakes in it. The liquid should be clear and colorless.
- **Do not** try to activate the clear needle guard before injecting.
- **Do not** insert your fingers into the opening of the clear needle guard.
- **Do not** use an Idacio pre-filled syringe that has been frozen or left in direct sunlight.
- **Do not** use the Idacio pre-filled syringe if it has been dropped or crushed, as the pre-filled syringe may be broken even if you cannot see the break.
Use a new pre-filled syringe instead.

Storage Information

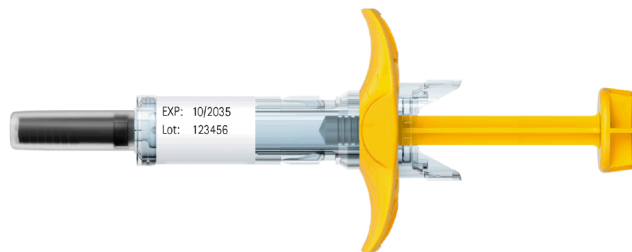
- Store the pre-filled syringe in its original box to protect it from light.
- Store the pre-filled syringe in a refrigerator between 2°C to 8°C.
- If needed, for example when traveling, the pre-filled syringe can be stored at room temperature for up to 14 days.

Get Familiar with your Idacio Pre-Filled Syringe

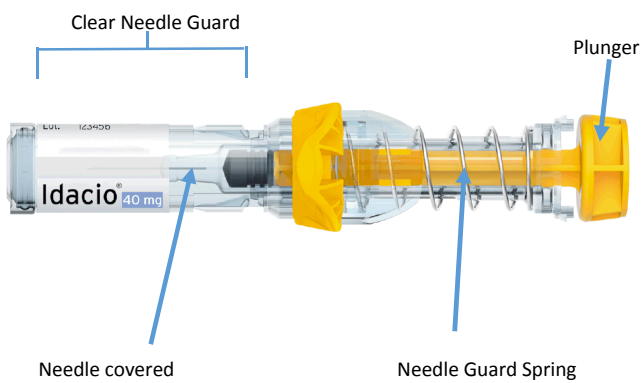
Before Use



Back view



After Use



Step 1 Prepare for your Injection

Each box of Idacio pre-filled syringe comes with two syringes.

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

1.2 You will also need (Figure A):

- an alcohol pad (included in the box)
- a cotton ball or gauze, and
- a sharps disposal container.

Open your sharps disposal container so it is ready to use.



Figure A

1.3 Remove the box from the refrigerator (Figure B).

1.4 Check the expiration date on the side of the box (Figure B).

Warning: Do not use if expiration date has passed.

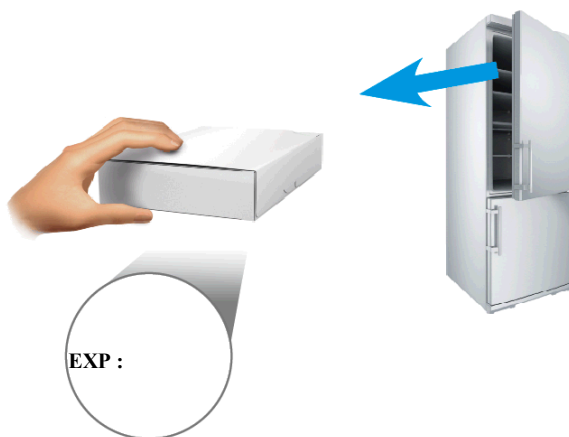


Figure B

1.5 Caution: Do not pick up the syringe by the plunger or the needle cap. Doing so could damage the syringe or activate the clear needle guard.

Take a syringe out of the original box:

- place two fingers on middle of the clear needle guard
- pull the syringe straight up and out of the packaging (Figure C).

Put it on a clean flat surface.

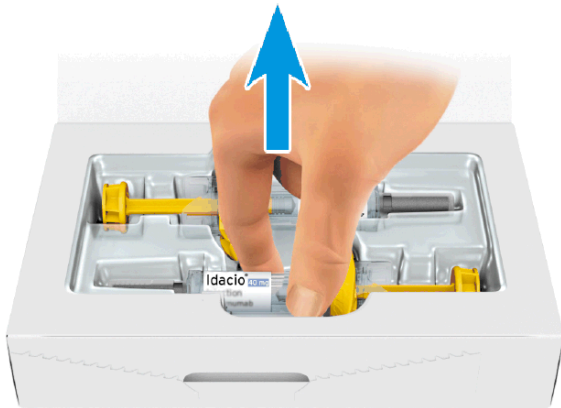


Figure C

1.6 Place the remaining syringe in its original box back in the refrigerator (Figure D).

Refer to Storage information for -how to store your unused syringe.

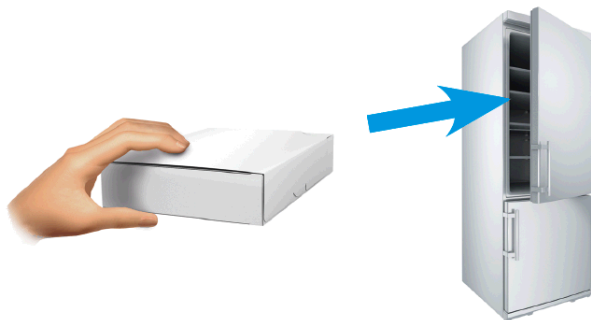


Figure D

1.7 Leave the syringe at room temperature for 30 minutes to allow the medicine to warm up.

Injecting cold medicine can be painful (Figure E).



Figure E

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

Warning: Do not remove the needle cap while allowing syringe to reach room temperature.

Step 2 Wash your Hands

2.1 Wash your hands well with soap and water (Figure F) and dry them.

Warning: Gloves will not replace the need for washing hands.



Figure F

Step 3 Wash your Hands

3.1 Check the syringe to make sure that:

- The syringe, the clear needle guard, and the needle cap are not cracked or damaged (Figure G).

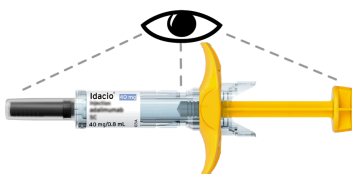


Figure G

- The needle cap is securely attached (Figure H).



Figure H

- The needle guard spring is not extended (Figure I).

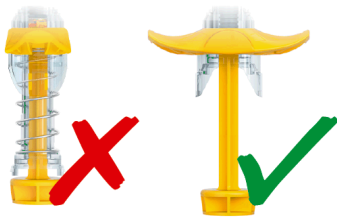


Figure I

Warning: Do not use the syringe if it shows any sign of damage.

If so, throw away the syringe in a sharps disposal container and contact your healthcare professional or pharmacist.

3.2 Check the liquid to make sure that:

- The liquid is clear, colorless, and free of particles (Figure J).

Warning: Do not use the syringe if liquid contains particles, or is cloudy or if it is colored or has flakes in it.

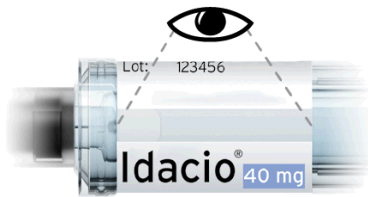


Figure J

3.3 Check the label to make sure that:

- The name on the syringe says Idacio (Figure K).
- The expiration date on syringe has not passed (Figure K).

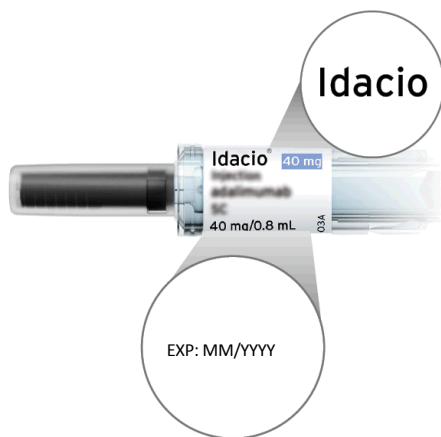


Figure K

Warning: Do not use the syringe if:

- The name on the syringe is not Idacio.
- The expiration date on the syringe has passed.

If so, throw away the syringe in a sharps disposal container and contact your healthcare professional or pharmacist.

Step 4

Choose the Injection Site

4.1 Choose an injection site (Figure L) on:

- Top of the thighs.
- Abdomen (inject at least 5 centimeters away from the belly button).



Figure L

4.2 Choose a different site (at least 2.5 centimeters away from the previous injection site) each time to reduce redness, irritation or other skin problems.

Warning: Do not inject into an area that is sore (tender), bruised, red, hard, scarred or where you have stretch marks.

Warning: If you have psoriasis, do not inject into any lesions or red, thick, raised or scaly patches.

Step 5

Clean the Injection Site

5.1 Wipe the skin of your injection site with an alcohol pad to clean it. (Figure M)

Warning: Do not blow on or touch the injection site after cleaning.

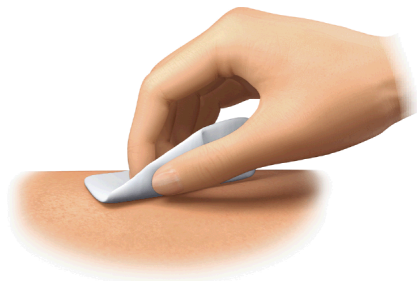


Figure M

Step 6

Give your Injection

6.1 Remove the needle cap

- Always hold the syringe by the clear needle guard.
- Hold the syringe upward and pull the needle cap straight off (Figure N).



Figure N

You may see drops of liquid at the needle tip.

- Throw away the needle cap.

Warning: Do not touch the needle.

6.2 Pinch the skin

- Hold the syringe like a pencil.
- With your other hand gently pinch skin (without squeezing) to avoid injecting into a muscle (Figure O).



Figure O

6.3 Insert the needle

- With a quick, short motion, push the needle all the way into the skin at an angle between 45° and 90° (Figure P).

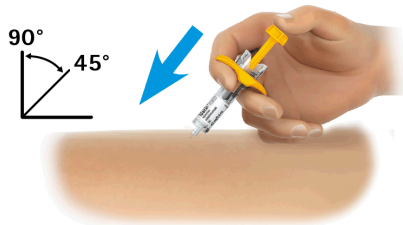


Figure P

- After the needle is inserted, release the pinched skin.

6.4 Inject

- Use your thumb to gently push plunger all the way down (Figure Q).

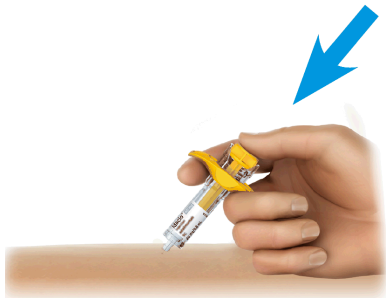


Figure Q

- Give plunger a final push to ensure the full dose has been injected (Figure R).
- Hold the syringe firmly without moving it, at the same angle (Figure R).



Figure R

Do not remove the needle from the skin when the plunger reaches the end.

Slowly release your thumb up.
This will allow the needle to move up into the clear needle guard and cover the entire needle (Figure S).

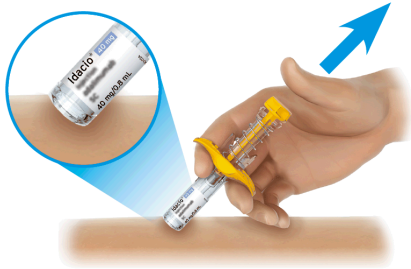


Figure S

Warning: Call your healthcare professional or pharmacist if:

- You did not inject the full dose or
- The clear needle guard does not activate after injecting.

Warning: **Do not** reuse a syringe in case of partial injection.

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

6.5 If there is blood or liquid on the injection site, gently press a cotton ball or gauze on the skin (Figure T).



Figure T

Step 7 Throw away your Syringe

7.1 Throw away your used syringe in a sharps disposal container right away after use (Figure U).



Figure U

Warning: Keep your sharps disposal container out of the reach of children.

Warning: Do not throw away the 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; that will keep sharps from coming out,
- Upright and stable during use,
- Leak-resistant and
- Properly labeled to warn of hazardous waste inside the container.

7.2 When your sharps disposal container is almost full, you will need to follow your local guidelines for the right way to dispose of your sharps disposal container.

Do not recycle your used sharps disposal container.

Step 8

Record your Injection

8.1 To help you remember when and where to do your next injection, you should keep a record of the dates and injection sites used for your injections (Figure V).



Figure V