

7. Instruction For Use

Idacio®

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



Note : images for illustration purposes only

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

Important Information

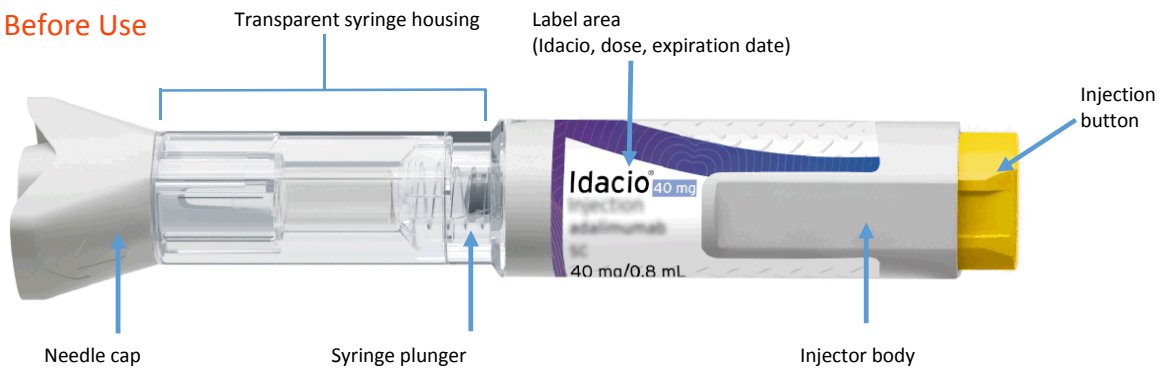
- Only use Idacio pre-filled pen if your healthcare professional has trained you how to use it correctly.
- The Idacio pre-filled pen comes as a ready to use single-use pre-filled pen to give a full dose of adalimumab.
- Always inject using the technique your healthcare professional taught you.
- Children under 12 years of age are not allowed to inject themselves and injection must be done by a trained adult.
- Keep the Idacio pre-filled pen out of the reach of children.
- **Do not** insert your fingers into the opening of the safety guard.
- **Do not** use an Idacio pre-filled pen that has been frozen or left in direct sunlight.
- Talk to your healthcare professional if you have any questions or concerns.

Storage Information

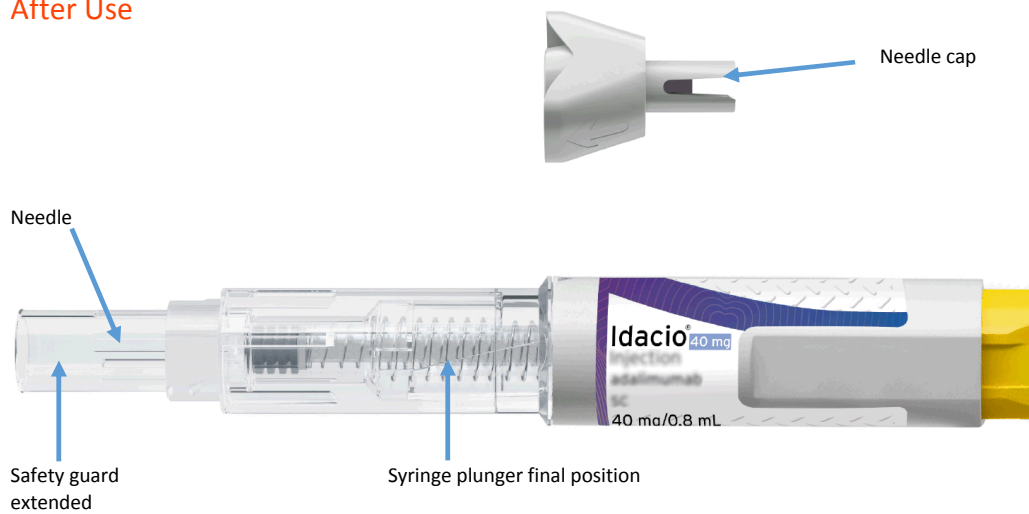
- Store the pre-filled pen in its original box to protect it from light.
- Store the pre-filled pen in a refrigerator between 2°C to 8°C.
- If needed, for example when traveling, the pre-filled pen can be stored at room temperature for up to 14 days.

Get Familiar with your Idacio Pre-filled pen

Before Use



After Use



Step 1

Prepare for your injection

Each box of Idacio pre-filled pen comes with two pre-filled pens.

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.



Figure A

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

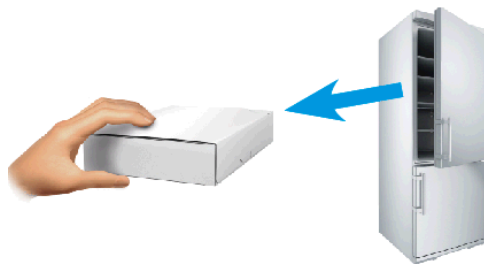


Figure B

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

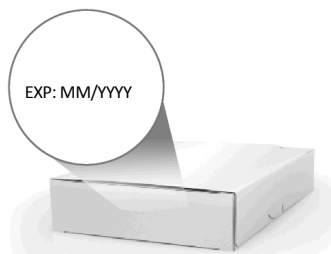


Figure C

Warning: Do not use if expiration date has passed.

1.5 Take a pre-filled pen out of the original box:

- place two fingers on the label area
- pull the pre-filled pen straight up and out of the packaging (Figure D).

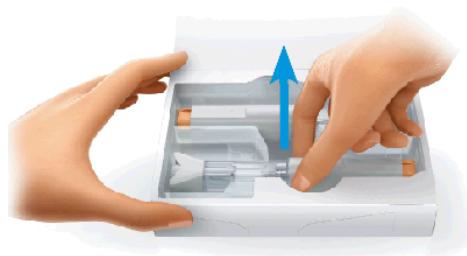


Figure D

Put it on a clean flat surface.

1.6 Place the remaining pre-filled pen in its original box back in the refrigerator (Figure E).

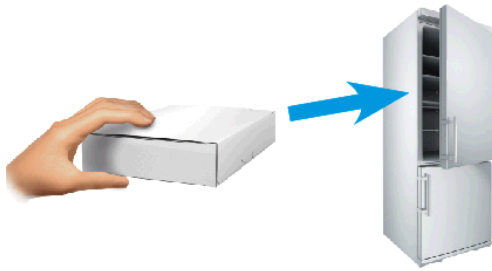


Figure E

Refer to Storage Information for how to store your unused pre-filled pen.

1.7 Leave the pre-filled pen at room temperature for at least 30 minutes to allow the medicine to warm up (Figure F).



Figure F

Injecting cold medicine may be painful.

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

Warning: Do not remove the needle cap until you are ready to inject.

Step 2 Wash your hands

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

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



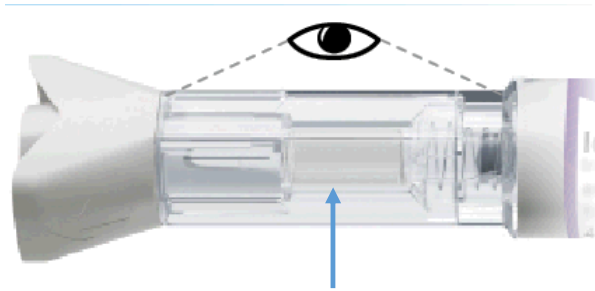
Figure G

Step 3

Check the Pre-filled Pen

3.1 Check the transparent syringe housing to make sure that:

- The liquid is clear, colorless, and free of particles (Figure H).
- The glass syringe is not cracked or broken (Figure H).



Transparent syringe housing

Figure H

Warning: Do not use the pre-filled pen if the liquid contains particles, or is cloudy or if it is colored, or has flakes in it or shows any sign of damage.

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

3.2 Check the label to make sure that:

- The name on the pre-filled pen says Idacio (Figure I).
- The expiration date on the pre-filled pen has not passed (Figure I).

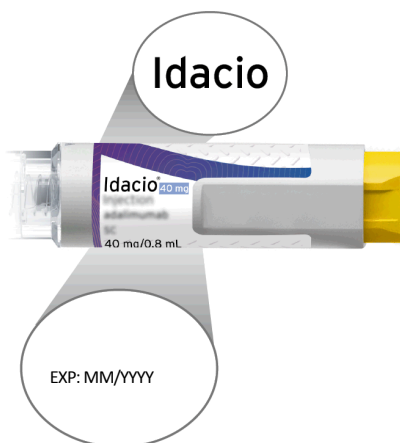


Figure I

Warning: Do not use the pre-filled pen if the name on the label is not Idacio and/or the expiration date on the label has passed.

If so, throw away the pre-filled pen 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 J) on:

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



Figure J

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 K).

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



Figure K

Step 6

Give your Injection

6.1 Remove the needle cap

- Hold the pre-filled pen upwards and pull the needle cap straight off (Figure L).



Figure L

You may see drops of liquid at the needle tip.

- Throw away the needle cap.

Warning: Do not twist the cap.

Warning: Do not recap the pre-filled pen.

6.2 Position the pre-filled pen

- Hold the pre-filled pen so that you can see the transparent syringe housing.
- Place your thumb above (not touching) the yellow injection button (Figure M).



Figure M

- Place the pre-filled pen against your skin at a 90° angle (Figure N).



Figure N

Before Injection

- Push and hold the pre-filled pen firmly against your skin until the safety guard is fully depressed. This will unlock the injection button (Figure O).

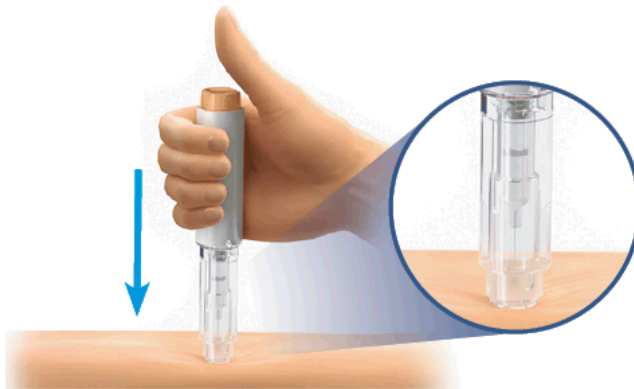


Figure O

Before Injection

6.3 Administer the Injection

- Push the injection button (Figure P). You will hear a loud click, which means the injection has started.
- Continue to **HOLD** the pre-filled pen firmly.
- **WATCH** the syringe plunger to make sure it moves all the way down to the bottom (Figure P).

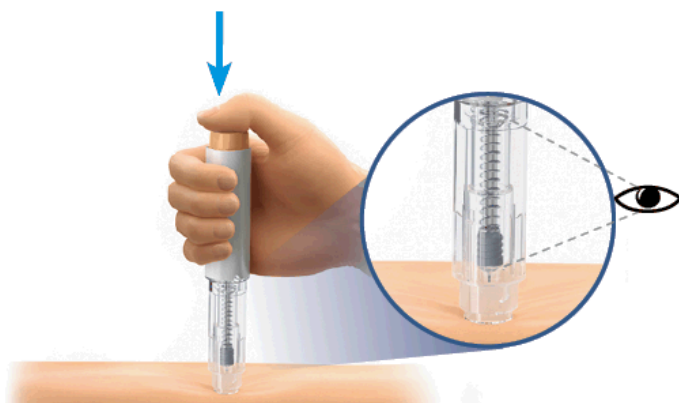


Figure P

After Injection

Warning: Do not lift the pre-filled pen from the skin until the plunger has moved all the way down and all the liquid has been injected.

- When the syringe plunger has moved to the bottom and has stopped moving, continue holding it for 5 seconds.
- Lift the pre-filled pen from your skin (Figure Q).

The safety guard will slide down and lock into place to protect you from the needle (Figure Q).

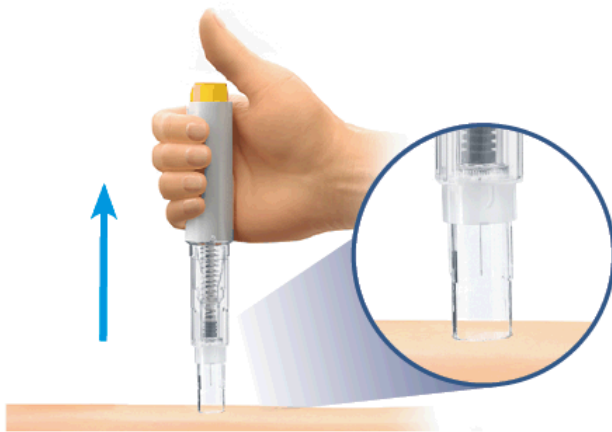


Figure Q

Warning: Call your healthcare professional or pharmacist if you have any problem.

6.4 If there is blood or liquid on the skin, treat the injection site by gently pressing a cotton ball or gauze on the site (Figure R).



Figure R

Step 7

Throw away your Pre-filled pen

7.1 Throw away your used pre-filled pen in a sharps disposal container right away after use (Figure S).



Figure S

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

Warning: Do not throw away the pre-filled pen 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 T).



Figure T