

Instructions for Use

Idacio[®]
(i-DAS-i-oh)

(adalimumab-aacf)
injection, for subcutaneous use
40 mg/0.8 mL
single dose prefilled pen



Read this Instructions for Use before using your IDACIO prefilled pen.

Do not try to inject IDACIO yourself until you have been shown the right way to give the injections and have read and understand this Instructions for Use. If your healthcare provider decides that you or a caregiver may be able to give your injections of IDACIO at home, you should receive training on the right way to prepare and inject IDACIO. It is important that you read, understand, and follow these instructions so that you inject IDACIO the right way. It is also important to talk to your healthcare provider to be sure you understand your IDACIO dosing instructions. To help you remember when to inject IDACIO, you can mark your calendar ahead of time. Call your healthcare provider if you or your caregiver have any questions about the right way to inject IDACIO.

Important information

- Read the Medication Guide that comes with your IDACIO prefilled pen for important information you need to know before using it.
- Call your healthcare provider if you have any questions about IDACIO or how to give your injection.
- IDACIO prefilled pen is for single-dose (one-time) use only.
- Do not share your IDACIO prefilled pen with another person.
You may give another person an infection or get an infection from them.

Storing IDACIO prefilled pens

- Store IDACIO prefilled pen in the original carton to protect it from light.
- Store IDACIO prefilled pen in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not** freeze IDACIO. Do not use IDACIO if frozen, even if it has been thawed.
- Refrigerated IDACIO may be used until the expiration date printed on the IDACIO carton, dose tray or pen. **Do not** use IDACIO after the expiration date.
- If needed, for example when traveling, IDACIO prefilled pen can be stored at room temperature between 68°F to 77°F (20°C to 25°C) for up to **28** days.
- Throw away IDACIO if it has been kept at room temperature and not been used within **28** days.
- Record the date you first remove IDACIO from the refrigerator in the spaces provided on the carton.

- Throw away (dispose of) the IDACIO prefilled pen in a sharps disposal container if it has been stored above 77°F (25°C). (See Step 7 “**Dispose of your prefilled pens**”).
- Do not store IDACIO in extreme heat or cold.
- Do not use IDACIO if the liquid is cloudy, discolored, or has flakes or particles in it.
- Do not drop or crush IDACIO.
- **Keep the IDACIO prefilled pen, injection supplies, and all other medicines out of the reach and sight of children.**

Using the IDACIO prefilled pen

- Only use IDACIO prefilled pen if your healthcare provider has instructed you on how to use it.
- **Do not** try to reuse the IDACIO prefilled pen.
- Before injecting, let IDACIO sit at room temperature for 15-30 minutes after removing it from the refrigerator.
- Always inject IDACIO using the technique your healthcare provider taught you.
- **Do not** use an IDACIO prefilled pen to give IDACIO to a child who weighs less than 66 pounds (30 kg).
- **Do not** insert your fingers into the opening of the safety guard.
- **Do not** use the prefilled pen if the new carton is open or damaged.
- **Do not** use an IDACIO prefilled pen that has been frozen or left in direct sunlight.
- **Do not** use and **do call** your healthcare provider or pharmacist if: you drop or crush your IDACIO prefilled pen.

Your Idacio prefilled pen

Before Use



Figure A

After Use



Figure B

Step 1 Prepare for your injection

1.1 Gather the supplies for your injection.

- You will need the following supplies for each injection of IDACIO (figure C). Find a clean flat surface, such as a table or countertop, in a well-lit area.
 - 1 Alcohol swab
 - 1 cotton ball or gauze (not included in your IDACIO carton)
 - 1 IDACIO prefilled pen (see figure A)
 - Puncture-resistant sharps disposal container for IDACIO prefilled pen disposal (not included in your IDACIO carton. (See Step 7 “**Dispose of used prefilled pens**”).



Figure C

If you do not have all the supplies you need to give yourself an injection, go to a pharmacy or call your pharmacist.

1.2 Remove the carton of IDACIO prefilled pens from the refrigerator (Figure D).

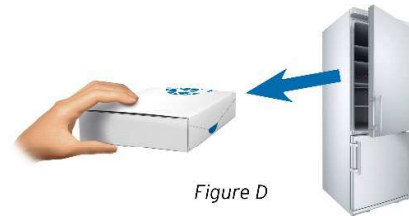


Figure D

1.3 Check the expiration date (EXP:) on the side of the carton (Figure E).

Do not use if the expiration date has passed.



Figure E

1.4 Take one IDACIO prefilled pen out of the original carton:

- Place two fingers on the label
- Pull the pen straight up and out of the packaging (Figure F)
- Place the capped pen on a clean flat surface

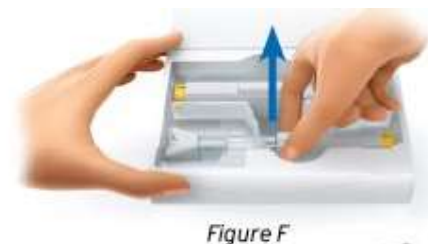


Figure F

1.5 Return the remaining pen in its original carton to the refrigerator (Figure G).

See “Storing IDACIO prefilled pens” for information on how to store your unused pen.

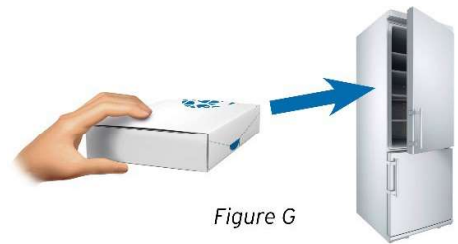


Figure G

1.6 Let the IDACIO prefilled pen sit at room temperature for 15-30 minutes before use to allow the medicine to reach room temperature (Figure H).

- **Do not** warm the pen in any other way, such as in a microwave, hot water, or direct sunlight.
- **Do not** remove the needle cap until you are ready to inject.



Figure H

Step 2 Wash your hands

2.1 Wash your hands well with soap and water and dry them with a clean towel (Figure I).



Figure I

Step 3 Check your prefilled pen

3.1 Check the transparent syringe housing to make sure that:

- the liquid is clear and colorless to pale yellow, and free of particles and flakes (Figure J).
- the syringe is not cracked or damaged. (Figure J).



Transparent syringe housing
Figure J

Do not use the prefilled pen if the liquid is cloudy or colored, if the liquid has particles or flakes in it, or if the prefilled pen looks damaged. Dispose of the pen in your sharps disposal container (see Step 7 “**Dispose of your prefilled pens**”) and call your healthcare provider or pharmacist.

3.2 Check the prefilled pen label to make sure that:

- the name on the pen says IDACIO (Figure K).
- the expiration date (EXP:) on the pen has not passed (Figure K).

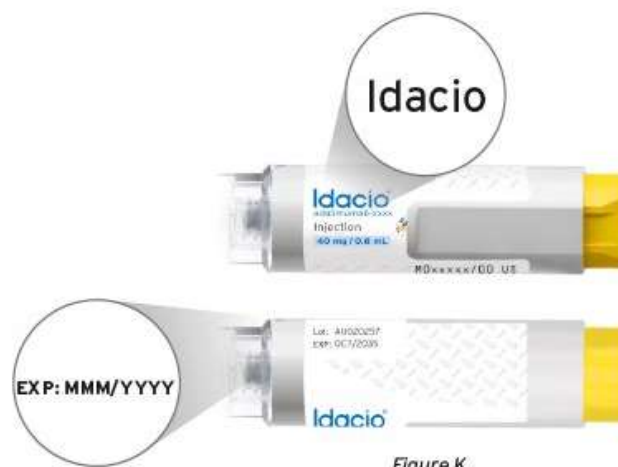


Figure K

Do not use the prefilled pen if the label does not have IDACIO on it or the expiration date has passed. Dispose of the pen in your sharps disposal container (see Step 7 “**Dispose of used prefilled pens**”) and call your healthcare provider or pharmacist.

Step 4 Choose the injection site

4.1 Choose an injection site on

- your stomach (abdomen). If you choose your stomach, do not use the area 2 inches around your belly button (navel) or
- the front of your thighs (Figure L)

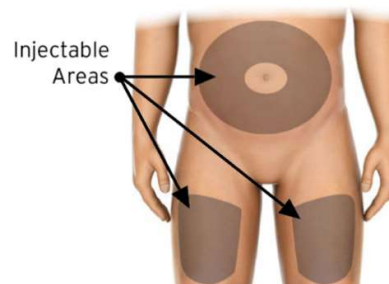


Figure L

Only inject into injection sites shown (Figure L).

4.2 Choose a different site (at least one inch away from your last injection site) for each injection to reduce redness, irritation or other skin problems. Each new injection should be given at least 1 inch from a site you used before.

- **Do not** inject IDACIO into skin that is sore (tender), bruised, red, hard, scarred or where you have stretch marks or tattoos.
- If you have psoriasis, **do not** inject into any lesions or red, thick, raised or scaly patches.
- **Do not** inject through your clothes.

Step 5 Clean the injection site

5.1 Wipe the skin of your injection site with an alcohol swab using a circular motion to clean it (Figure M).

Let the skin dry before injecting.

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



Figure M

Step 6 Give your injection

6.1 Remove the needle cap

- Hold the pen upwards.
- Remove the needle cap with your other hand by pulling the cap straight off (Figure N).

Do not twist the cap.

Do not insert your fingers into the opening of the safety guard

You may see a few drops of liquid at the needle tip. This is normal

- Dispose of the needle cap in your sharps disposal container.



Figure N

6.2 Position the pen

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



Figure O

- Place the pen straight and flat against your skin **at a 90° angle** (Figure P).

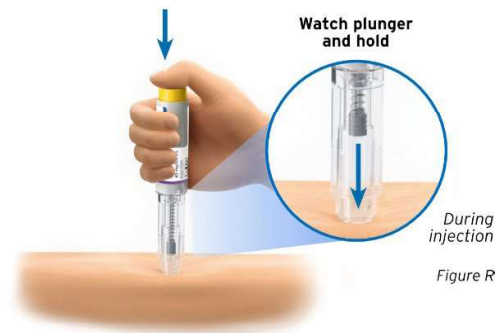


6.3 Administer the Injection

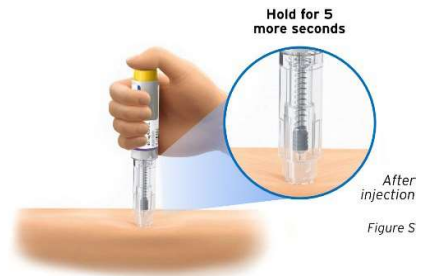
- Push and hold the pen **firmly** against your skin until the safety guard is fully pushed down. This will unlock the injection button (Figure Q).



- Push the injection button with your thumb (Figure R). You will hear a loud ‘click’, which means the injection has started.
- **Continue to hold** the pen firmly.
- **Watch the syringe plunger** to make sure it moves all the way down to the bottom of the transparent syringe housing (Figure R).

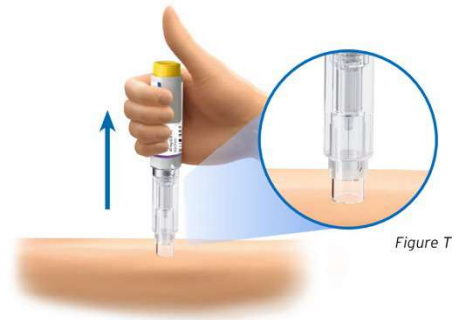


- **Continue holding the pen for 5 seconds** after the syringe plunger has reached the bottom of the transparent syringe housing. (Figure S)



Do not lift the pen from the skin until the syringe plunger has moved all the way down and you have waited 5 seconds.

- Lift the pen from your skin (Figure T). The safety guard will slide down and lock into place to cover the needle (Figure T).



Do not recap the pen.

Call your healthcare provider or pharmacist if you have any problem with your injection.

- 6.4** If there is blood or liquid on the injection site, gently press a cotton ball or gauze on the skin (Figure U).

Do not rub the injection site

You may use an adhesive bandage if needed.



Figure U

Step 7 Dispose of your prefilled pens

- 7.1** Put your used prefilled pens in a FDA-cleared sharps disposal container right away after use (Figure V).

Do not throw away (dispose of) prefilled pens in your household trash.

- If you do not have a 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 dispose of 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>



Figure v

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.

Always keep the sharps container out of the reach of children.

Step 8 Document your injection site and date administered

8.1 To help you remember when and where on your body to give your next injection, keep a record of the dates and injection sites used for your injections (Figure W).

Record the date and injection site



Figure W

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