

# Instructions for Use

 **Hulio**<sup>®</sup> PEN (hue' lee oh)  
(adalimumab-fkjp) injection



for subcutaneous use 40 mg/0.8 mL

## Single-Dose Prefilled Pen

### For subcutaneous (under the skin) use only

**Read these instructions carefully before using your Pen.** This information does not replace talking to your healthcare provider about your medical condition and your treatment.

**Do not** try to inject HULIO 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 HULIO at home, you should receive training on the right way to prepare and inject HULIO. It is important that you read, understand, and follow these instructions so that you inject HULIO the right way. It is also important to talk to your healthcare provider to be sure you understand your HULIO dosing instructions. To help you remember when to inject HULIO, you

can mark your calendar ahead of time. Call your healthcare provider if you or your caregiver has any questions about the right way to inject HULIO.

**For Questions or Assistance,  
Call Biocon Biologics at 1-833-986-1468**

**Caution:** Never put your thumb, fingers, or hand over the orange activator after cap is removed. Never press or push the Orange Activator with your thumb, fingers, or hand. The Orange Activator is where the needle comes out. If accidental injection to your fingers or hands occurs, apply first-aid and either call your healthcare provider or go to the nearest hospital emergency room if needed.

**Dosage:** HULIO PEN is for single dose (1-time) use only.

## IMPORTANT

**Do not** use HULIO if frozen, even if it has been thawed.

**Do not** uncap your HULIO PEN until you are ready to inject and will not be interrupted.

**Do not** recap. Recapping your HULIO PEN can damage the needle.

A loud “click” will occur when the Orange Activator is pressed down to deliver your dose of HULIO.

- You must practice injecting with your healthcare provider or nurse so that you are not surprised

by this “click” sound when you give yourself injections.

- This 1st “click” sound means the start of the injection.
- You will know that the injection has finished when all three of these have occurred:
  - A 2nd “click” was heard, and
  - Orange Indicator has stopped and completely blocked the Viewing Window, and
  - 10 seconds has passed.

## Parts of the HULIO PEN

See Figure A.

### Storing and Handling the HULIO PEN

Store Pen in a refrigerator between 36°F to 46°F (2°C to 8°C) in its original carton.

- Refrigerated HULIO may be used until the expiration date.
- **Do not** freeze the Pen.
- **Do not** expose the Pen to extreme heat or cold, such as a hot car, or a freezing car overnight.

If needed, for example when traveling, HULIO may be stored at room temperature up to 77°F (25°C) for a period of up to 14 days, with protection from light. Discard (throw away) HULIO if not used within the 14 day period. Record the date on the carton and dose tray when HULIO is first removed from the refrigerator.

- **Protect from light.**
- **Take care not to drop or crush.**
- **Do not** use if the Pen is damaged or broken.
- **Keep HULIO, injection supplies, and all other medicines out of the reach of children.**

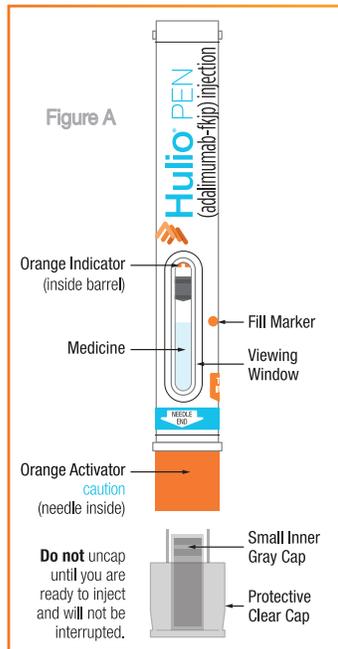
### Gather Supplies for Injection

Find a quiet area with a well-lit, clean and flat work surface and gather all the supplies you will need to give yourself or receive an injection.

#### Supplies you will need:

##### Included in HULIO carton

- 1 Pen (taken from refrigerator 30 minutes prior to intended injection time to allow Pen to reach room temperature.)
- 1 alcohol prep



## Not included in HULIO carton

- 1 FDA-cleared sharps disposal container or puncture resistant container. (See “How should I dispose of the used HULIO PEN and Cap?” Section in Step 7 at the end of this Instructions for Use).
- 1 gauze pad or cotton ball

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

### Preparing the Pen

Remove the Pen from the refrigerator 30 minutes before using.

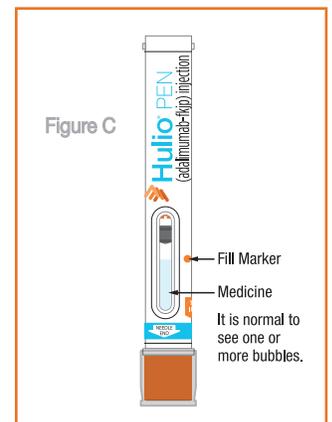
- Make sure the name HULIO appears on the Pen label.
- **Check the expiration date printed on the Pen (See Figure B).**
- **Do not** use the Pen past the expiration date.



- **Check that the HULIO PEN has not been frozen or left in direct sunlight.**
- **Let the Pen reach room temperature.**
- **Do not** use external heat sources such as hot water, direct sunlight, or microwave to warm the Pen.
- **Do not** put the Pen back in refrigerator after it has reached room temperature.

### Check the Viewing Window to make sure:

- **Medicine is at or near the Fill Marker.** You may need to shake gently to see liquid.
- **Medicine is clear and colorless to pale brownish-yellow (See Figure C).**



- **Do not** use the Pen if medicine is not near the Fill Marker. Use another Pen or contact your healthcare provider.
- **Do not** use the Pen if it is cloudy, discolored, or has particles in it.

### Choosing and Preparing Injection Site

Your healthcare provider should show you proper injection site techniques.

- **Recommended subcutaneous (under the skin) injection sites are:**
  - the front of the thighs, or
  - the abdomen (belly)
  - **Do not** use area within 2 inches of belly button (See Figure D).



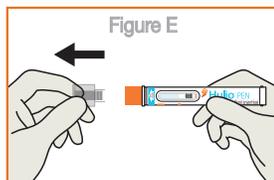
- **You should rotate and change your injection site each time you give an injection.**
- Stay at least 1 inch from a previous site used.
- **Do not** inject into areas where the skin is tender, bruised, red, hard, scarred or has stretch marks.
- If you have psoriasis, **do not** inject into any raised, thick, red, or scaly skin patches or lesions.
- **Do not** inject through clothes. Roll back any clothing that may get in the way of the injection site.
- **Wash your hands with soap and water.**
- **Wipe the chosen injection site using a circular motion with an alcohol prep.** Wait for it to dry on its own, do not blow dry.
- **Do not** touch this injection site again before receiving your injection.

## GIVING THE INJECTION

**Caution:** Injection process must be completed without interruption. Read all steps first before beginning injection.

### STEP 1 – Uncap

- **Pull straight on the protective clear cap to uncap the Pen (See Figure E). Do not twist.**
- A few drops of liquid may come out of the needle, this is normal.
- Throw away the protective clear cap in an FDA-cleared sharps container or puncture resistant container (See “**How should I dispose of the used HULIO PEN and Cap?**” in Step 7). **Do not** put your protective clear cap in the household trash.

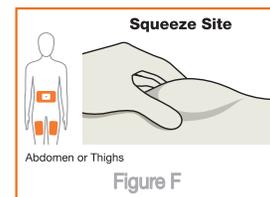


### Important:

- **Do not** put the protective clear cap back on the Pen. This can damage the needle.
- **Do not** touch the Orange Activator with your fingers (this is where the needle comes out).

### Step 2 – Squeeze and Hold Injection Site

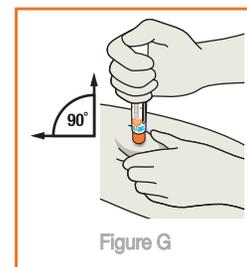
The thigh injection site is shown here (See Figure F). Perform these steps the same way for abdomen (belly) injection sites.



- **Squeeze the injection site to create a raised area, and hold that area firmly, until the injection is complete.**
- See “**Choosing and Preparing Injection Site**” or talk to your healthcare provider for injection site assistance.

### Step 3 – Place Pen

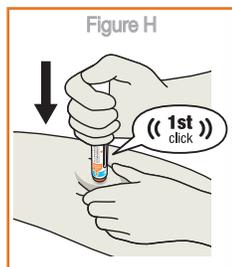
- **Place the Orange Activator end onto the injection site.**
- **Keep the Pen held straight (90° angle) and flat to the raised injection site area, and with the Viewing Window visible to you (See Figure G).**



- Be careful to place the Pen so that it will not inject into your fingers holding the injection site.

### Step 4 – Begin Injection

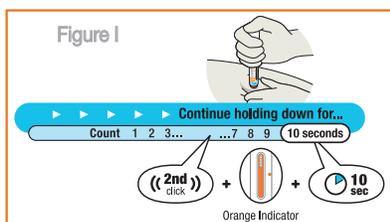
- **Firmly push the body of the Pen down against the injection site to engage the Orange Activator and begin injection (See Figure H).** Try not to cover the Viewing Window.
- **Continue pushing down after hearing the 1st “click”.** This 1st “click” sound signals the start of the injection.
- **In the Viewing Window, the Orange-Indicator will move to show the progress of the injection.**
- **Do not** move, twist, or rotate the Pen during injection.



### Step 5 – Hold Down for 2nd “click”, Orange Indicator and 10 Seconds

Continue pushing the body of the Pen down against the injection site until:

- A 2nd “click” was heard, and
- Orange Indicator has stopped and completely blocked the Viewing Window (See Figure I), and
- 10 seconds has passed.

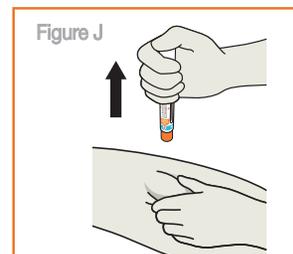


**Caution:** Make sure all three of these have occurred to ensure all medicine was delivered. If the needle did not retract or you do not think you received the full dose contact your healthcare provider for assistance.

### Step 6 – End of Injection, Remove HULIO PEN

- **Pull Pen straight away from injection site (See Figure J).**

- There may be a small amount of liquid on the injection site. This is normal. If slight bleeding occurs from the injection site, press a gauze pad or cotton ball lightly against the site for a few seconds.
- **Do not** rub the injection site.



### Dispose of the HULIO PEN and Cap

Put the used Pen and Cap in an FDA-cleared sharps disposal container or puncture resistant container to avoid injury (See “How should I dispose of the used HULIO PEN and Cap?” in Step 7).

Pen is for single-dose only.

**Do not** reuse the Pen if all of the medicine was not injected.

**Do not** try to recap the Pen as it could lead to a needle stick injury.

### Step 7 – How should I dispose of the used HULIO PEN and Cap?

- **Put your used Pen and cap in an FDA-cleared sharps disposal container right away after use.**
- **Do not throw away (dispose of) the Pen or Cap 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 your sharps disposal container. 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 recycle your used sharps disposal container.

### **Step 8 – Injection Diary**

Write down the date you received your injection and the injection site used in the injection diary below.

## **INJECTION DIARY**

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Date	Injection Site Used

**Customer Service**  
**For Questions or Assistance, Call Biocon Biologics at 1-833-986-1468**

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