

Instructions for Use

 **Hulio**[®] (hue' lee oh)
(adalimumab-fkjp) injection



for subcutaneous use 20 mg/0.4 mL and 40 mg/0.8 mL

Single-Dose Prefilled Syringe

For subcutaneous (under the skin) use only
Read these instructions carefully before using your Syringe. This information does not replace talking to your doctor 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**

Dosage: HULIO Prefilled Syringe is for single dose (1-time) use only.

IMPORTANT

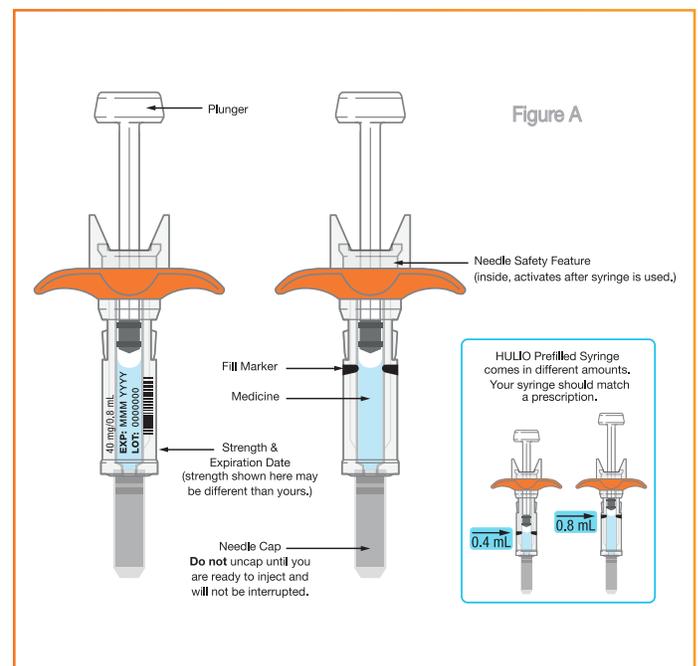
- **Do not** use HULIO if frozen, even if it has been thawed.
- **Do not** uncap your HULIO Prefilled Syringe until you are ready to inject and will not be interrupted.
- **Do not** recap. Recapping your HULIO Prefilled Syringe can damage the needle.

Parts of the HULIO Prefilled Syringe

See Figure A.

Storing and Handling the Syringe

- **Store Syringe 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 Syringe.
- **Do not** expose the Syringe 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 Syringe 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 the HULIO carton

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

Not included in HULIO carton

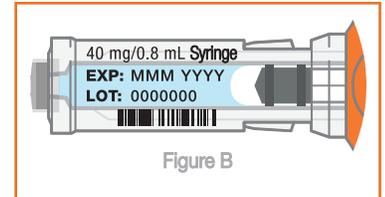
- 1 FDA-cleared sharps disposal container or puncture resistant container (See “**How should I dispose of the used HULIO Prefilled Syringe and Needle Cap?**” Section in Step 6 at the end of this Instructions for Use.)
- 1 gauze pad or cotton ball

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

Preparing the Syringe

Remove Syringe from refrigerator 30 minutes before using.

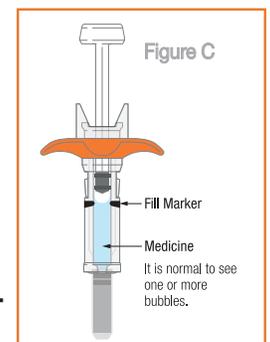
- Make sure the name HULIO appears on the Syringe label.
- **Check the expiration date printed on the Syringe (See Figure B).**



- **Do not** use the Syringe past the expiration date.
- **Check that the Syringe has not been frozen or left in direct sunlight.**
- **Let the Syringe reach room temperature.**
- **Do not** use external heat sources such as hot water, direct sunlight, or microwave to warm the Syringe.
- **Do not** put the Syringe back in the 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 Syringe if medicine is not near the Fill Marker. Use another Syringe or contact your healthcare provider.

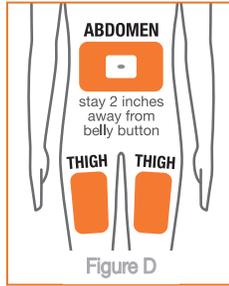
Do not use the Syringe if it is cloudy, discolored, or has particles in it.

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.



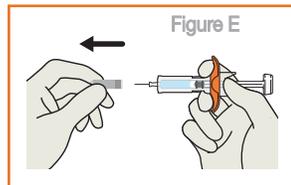
- If you have psoriasis, **do not** inject into any raised, thick, red, or scaly skin patches or lesions.
- **Do not** inject through clothes. Roll back any clothing that may get in the way of the injection site.
- **Wash your hands with soap and water.**
- **Wipe the chosen injection site using a circular motion with an alcohol prep.** Wait for it to dry on its own, do not fan or 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 Needle Cap to uncap Syringe (See Figure E). Do not twist.**
- A few drops of liquid may come out of the needle, this is normal.
- It is normal to see one or more air bubble(s).
- Throw away the Needle Cap in an FDA-cleared sharps container or puncture resistant container (See “**How should I dispose of the used HULIO Prefilled Syringe and Needle Cap**” in Step 6). **Do not** put your protective clear cap in the household trash.

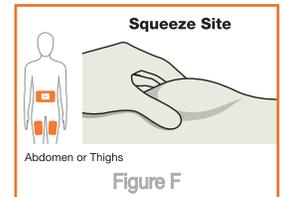


Caution:

- **Do not** recap Syringe.
- **Do not** remove air bubble(s).
- **Do not** pull back on the Plunger at any time.
- **Do not** touch the needle with your fingers or let the needle touch anything.
- **Do not** use Syringe if dropped after uncapping.

STEP 2 – Squeeze and Hold Injection Site

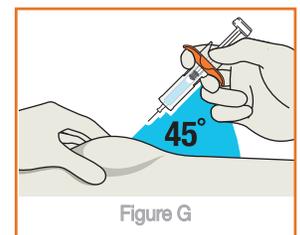
The thigh injection site is shown here (See Figure F). Perform these steps the same way for abdomen (belly) injection sites.



- **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 – Insert Needle Into Site

At a 45° angle to the injection site, with your other hand use a quick dart-like motion to insert the needle into the site (See Figure G).

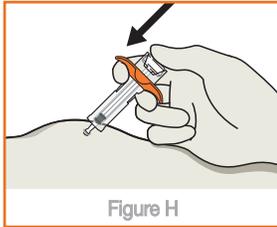


Be careful to insert the needle so that it will not inject into your fingers holding the injection site.

STEP 4 – Inject Medicine

After the needle is in, let go of squeezing the injection site.

Slowly push the plunger all the way down with your thumb until all the medicine is injected and the Syringe is empty (See Figure H).



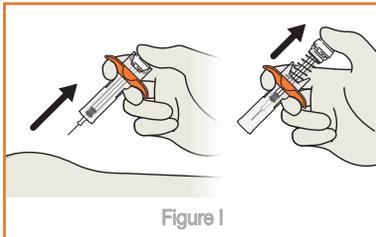
If the plunger is not pressed all the way down the Needle Safety Feature will not activate afterwards to cover the needle.

Do not move, twist, or rotate Syringe during injection.

STEP 5 – End of Injection, Remove Syringe

Pull the Syringe away from the injection site, then release your thumb from the plunger.

The needle will retract and the Needle Safety Feature will cover the needle (See Figure I).



Caution: If the needle did not retract or you do not think you received the full dose, contact your healthcare provider for assistance.

If the needle does not retract, carefully place the Syringe into a sharps or puncture resistant container to avoid injury.

- 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 Syringe and Needle Cap
Put the used Syringe and Needle Cap in an FDA-cleared sharps disposal container or puncture resistant container to avoid injury (See “How should I dispose of the used HULIO Prefilled Syringe and Needle Cap?” in Step 6).

Syringe is for single-dose only.

Do not reuse the Syringe even if all of the medicine was not injected.

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

STEP 6 – How should I dispose of the used HULIO Prefilled Syringe and Needle Cap?

- **Put your used Syringe and Needle Cap in an FDA-cleared sharps disposal container right away after use.**
- **Do not throw away (dispose of) Syringe or Needle 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 syringes. 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 7 – Injection Diary

Write down the date you received your injection and the injection site used in the injection diary on the next page.

INJECTION DIARY

Date	Injection Site Used

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

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