

INSTRUCTIONS FOR USE

YESINTEK(Yes-in-tek) (ustekinumab-kfce) injection, for subcutaneous use



Instructions for injecting YESINTEK from a vial.

Read this Instructions for Use before you start using YESINTEK. Your doctor or nurse should show you how to prepare, measure your dose, and give your injection of YESINTEK the right way.

If you cannot give yourself the injection:

- ask your doctor or nurse to help you, or
- ask someone who has been trained by a doctor or nurse to give your injections.

Do not try to inject YESINTEK yourself until you have been shown how to inject YESINTEK by your doctor, nurse, or health professional.

Important information

- Before you start, check the carton to make sure that it is the right dose. You will have either 45 mg or 90 mg as prescribed by your doctor.
 - If your dose is 45 mg or less you will receive one 45 mg vial.
 - If your dose is 90 mg, you will receive two 45 mg vials **and you will need to give yourself two injections, one right after the other.**
- Children 12 years of age and older weighing less than 132 pounds require a dose lower than 45 mg.
- Check the expiration date on the vial and carton. If the expiration date has passed, do not use it. If the expiration date has passed, call your doctor or pharmacist, or call Biocon Biologics at 1-833-986-1468 for help.
- Check the vial for any particles or discoloration. Your vial should look clear and colorless to pale yellow solution.
- Do not use if it is frozen, discolored, cloudy or has large particles. Get a new vial.
- **Do not shake the vial at any time.** Shaking your vial may damage your YESINTEK medicine. If your vial has been shaken, do not use it. Get a new vial.
- Do not use a YESINTEK vial more than one time, even if there is medicine left in the vial. After the rubber stopper is punctured, YESINTEK can become contaminated by harmful bacteria which could cause an infection if re-used. Therefore, throw away any unused YESINTEK after you give your injection.
- Safely throw away (dispose of) YESINTEK vials after use.
- Do not re-use syringes or needles. See **“Step 6: Dispose of needles and syringes.”**
- To avoid needle-stick injuries, **do not** recap needles.

Storage information

- Store YESINTEK vials in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Store YESINTEK vials standing up straight.
- Store YESINTEK in the original carton to protect from light until the time of use.

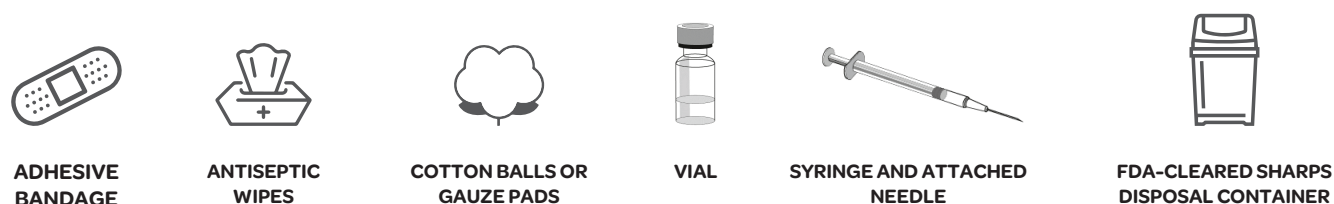
- Do not freeze YESINTEK.
- Do not shake YESINTEK.
- Do not use YESINTEK after the expiration date on the carton or on the vial.

**Gather the supplies you will need to prepare YESINTEK and to give your injection.
(See Figure A)**

You will need:

- a syringe with the needle attached, you will need a prescription from your healthcare provider to get syringes with the needles attached from your pharmacy.
- antiseptic wipes
- cotton balls or gauze pads
- adhesive bandage
- your prescribed dose of YESINTEK
- FDA-cleared sharps disposal container. See **“Step 6: Dispose of needles and syringes.”**

Figure A



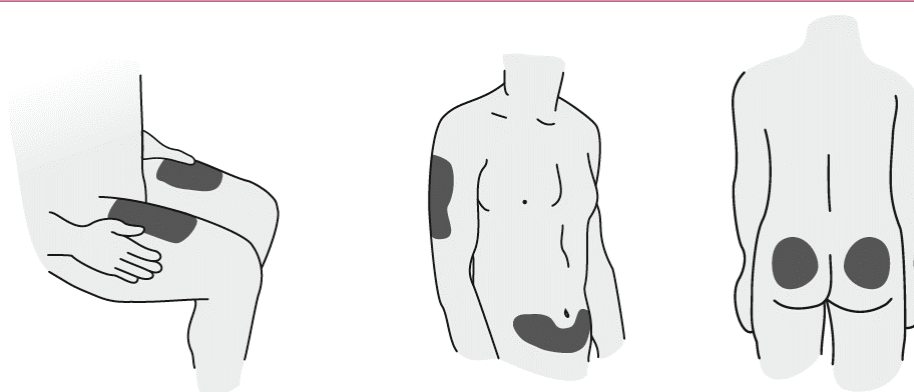
Step 1: Prepare the injection.

- Choose a well-lit, clean, flat work surface.
- Wash your hands well with soap and warm water.

Step 2: Prepare your injection site

- Choose an injection site around your stomach area (abdomen), buttocks, and upper legs (thighs). If a caregiver is giving you the injection, the outer area of the upper arms may also be used. **(See Figure B)***
- **Use a different injection site for each injection. Do not** give an injection in an area of the skin that is tender, bruised, red or hard.
- Clean the skin with an antiseptic wipe where you plan to give your injection.
- **Do not** touch this area again before giving the injection. Let your skin dry before injecting.
- **Do not** fan or blow on the clean area.

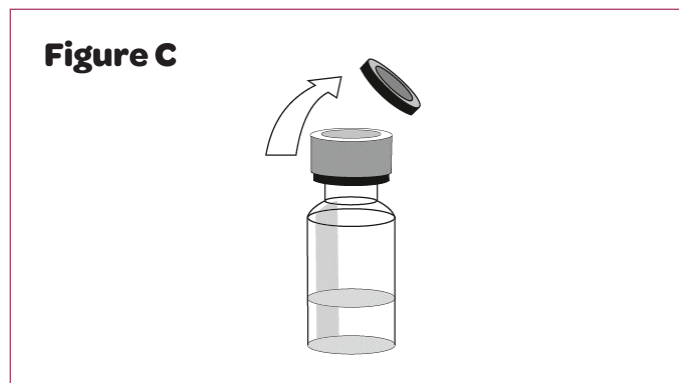
Figure B



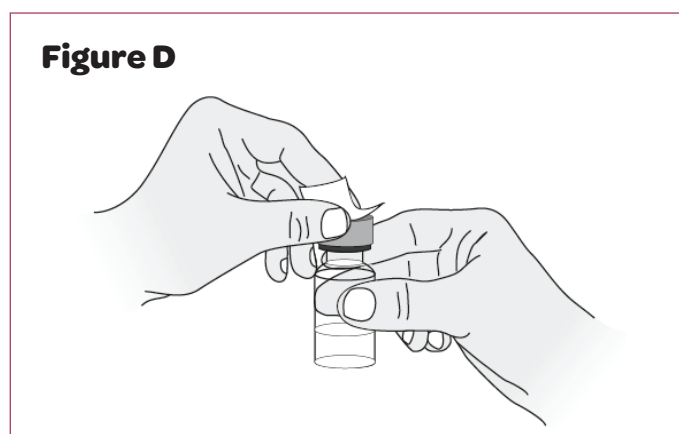
*Areas in gray are recommended injection sites

Step 3: Prepare the vial.

- Remove the cap from the top of the vial. Throw away the cap but do not remove the rubber stopper. **(See Figure C)**



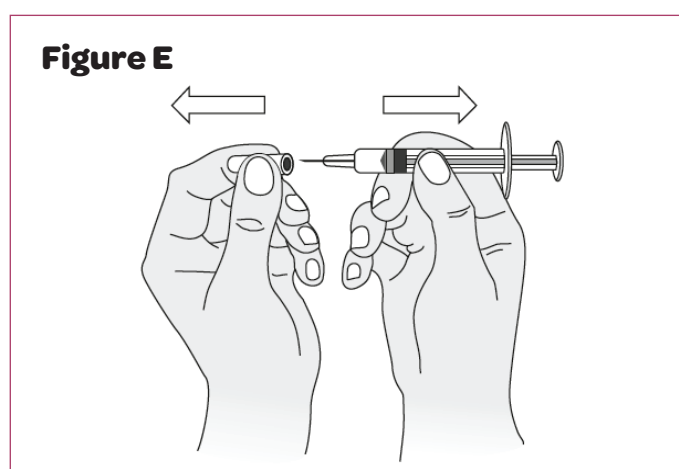
- Clean the rubber stopper with an antiseptic swab. **(See Figure D)**



- Do not touch the rubber stopper after you clean it.
- Put the vial on a flat surface.

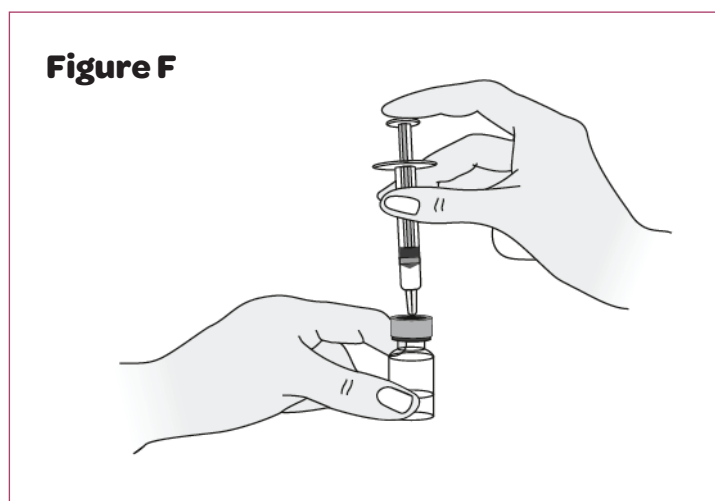
Step 4: Prepare the needle

- Pick up the syringe with the needle attached.
- Remove the cap that covers the needle. **(See Figure E)**
- Throw the needle cap away. Do not touch the needle or allow the needle to touch anything.

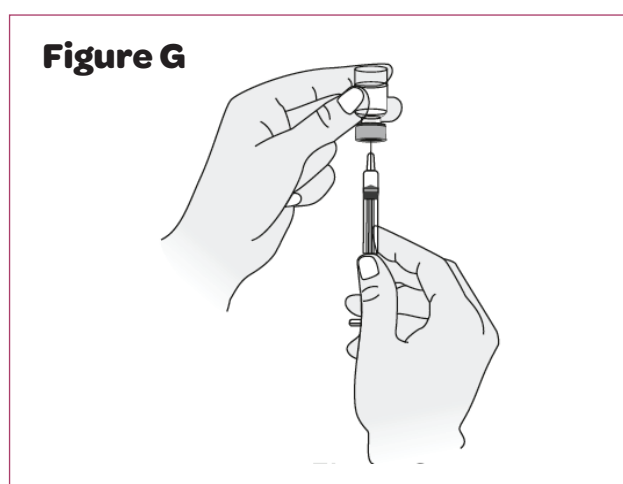


- Carefully pull back on the plunger to the line that matches the dose prescribed by your doctor.
- Hold the vial between your thumb and index (pointer) finger.

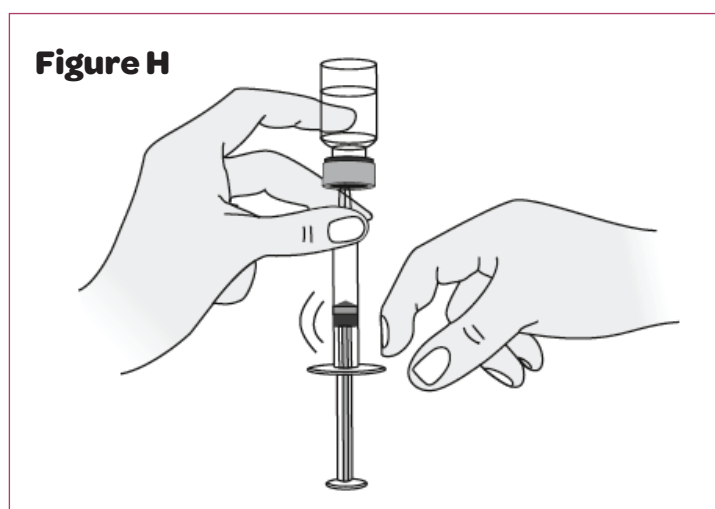
- Use your other hand to push the syringe needle through the center of the rubber stopper. **(See Figure F)**



- Push down on the plunger until all of the air has gone from the syringe into the vial.
- Turn the vial and the syringe upside down. **(See Figure G)**
- Hold the YESINTEK vial with one hand.
- It is important that the needle is always in the liquid in order to prevent air bubbles forming in the syringe.
- Pull back on the syringe plunger with your other hand.
- Fill the syringe until the black tip of the plunger lines up with the mark that matches your prescribed dose.

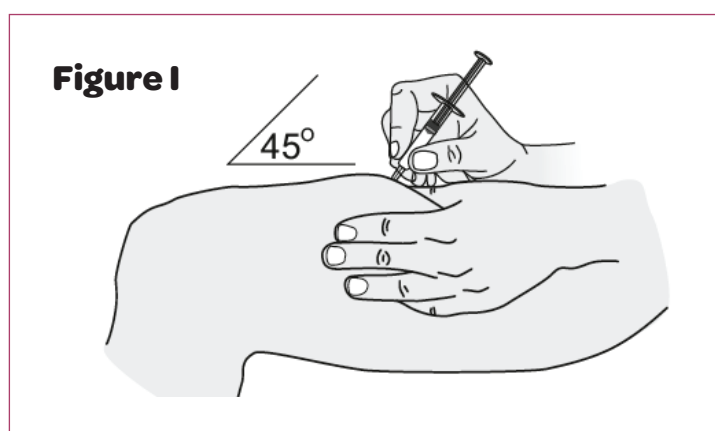


- **Do not remove the needle from the vial.** Hold the syringe with the needle pointing up to see if it has any air bubbles inside.
- If there are air bubbles, gently tap the side of the syringe until the air bubbles rise to the top. **(See Figure H)**
- Slowly press the plunger up until all of the air bubbles are out of the syringe (but none of the liquid is out).
- Remove the syringe from the vial. Do not lay the syringe down or allow the needle to touch anything.

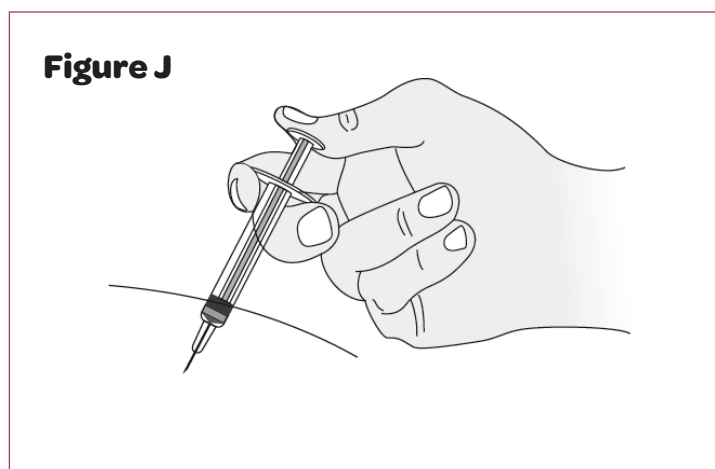


Step 5: Inject YESINTEK

- Hold the barrel of the syringe in one hand, between the thumb and index fingers.
- **Do not** pull back on the plunger at any time.
- Use the other hand to gently pinch the cleaned area of skin. Hold firmly.
- Use a quick, dart-like motion to insert the needle into the pinched skin at about a 45-degree angle. **(See Figure I)**



- Push the plunger with your thumb as far as it will go to inject all of the liquid. Push it slowly and evenly, keeping the skin gently pinched.
- When the syringe is empty, pull the needle out of your skin and let go of the skin. **(See Figure J)**



- When the needle is pulled out of your skin, there may be a little bleeding at the injection site. This is normal. You can press a cotton ball or gauze pad to the injection site if needed. Do not rub the injection site. You may cover the injection site with a small adhesive bandage, if necessary.


If your dose is 90 mg, you will receive two 45 mg vials and you will need to give yourself a second injection right after the first. Repeat Steps 1-5 using a new syringe. Choose a different site for the second injection.

Step 6: Dispose of the needles and syringes.

- **Do not** re-use a syringe or needle.
- To avoid needle-stick injuries, do not recap a needle.
- Put your needles and syringes in a FDA-cleared sharps disposal container right away after use.
- **Do not throw away (dispose of) loose needles and syringes 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 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 labelled 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 local or state laws about how to throw away syringes and needles. 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 dispose of your sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your sharps disposal container.

- Throw away the vial into the container where you put the syringes and needles.
- If you have any questions, talk to your doctor or pharmacist.

Keep YESINTEK and all medicines out of the reach of children.



Manufactured by:

Biocon Biologics Inc.

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

INJECTION DIARY

Date	Injection Site Used

Customer Service

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

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