

INSTRUCTIONS FOR USE

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



Instructions for injecting YESINTEK using a prefilled syringe.

Read this Instructions for use before you start using YESINTEK. Your doctor or nurse should show you how to prepare 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, you will receive one 45 mg prefilled syringe.
 - If your dose is 90 mg, you will receive either one 90 mg prefilled syringe or two 45 mg prefilled syringes. **If you receive two 45 mg prefilled syringes for a 90 mg dose, you will need to give yourself two injections, one right after the other.**
- Children 12 years of age and older with psoriasis who weigh 132 pounds or more may use a prefilled syringe.
- Check the expiration date on the prefilled syringe and carton. If the expiration date has passed or if the prefilled syringe has been kept at room temperature up to 86°F (30°C) for longer than a maximum single period of 30 days or if the prefilled syringe has been stored above 86°F (30°C), do not use it. If the expiration date has passed or if the prefilled syringe has been stored above 86°F (30°C), call your doctor, pharmacist, or call Biocon Biologics at 1-833-986-1468 for help.
- Make sure the syringe is not damaged.
- Check your prefilled syringe for any particles or discoloration. Your prefilled syringe should look clear and colorless to pale yellow.
- Do not use if it is frozen, discolored, cloudy or has large particles. Get a new prefilled syringe.
- **Do not shake the prefilled syringe at any time.** Shaking your prefilled syringe may damage your YESINTEK medicine. If your prefilled syringe has been shaken, do not use it. Get a new prefilled syringe.
- To reduce the risk of accidental needle sticks, each prefilled syringe has a needle guard that is automatically activated to cover the needle after you have given your injection. Do not pull back on the plunger at any time. Do not attempt to remove the needle safety guard from the prefilled syringe.

Storage information

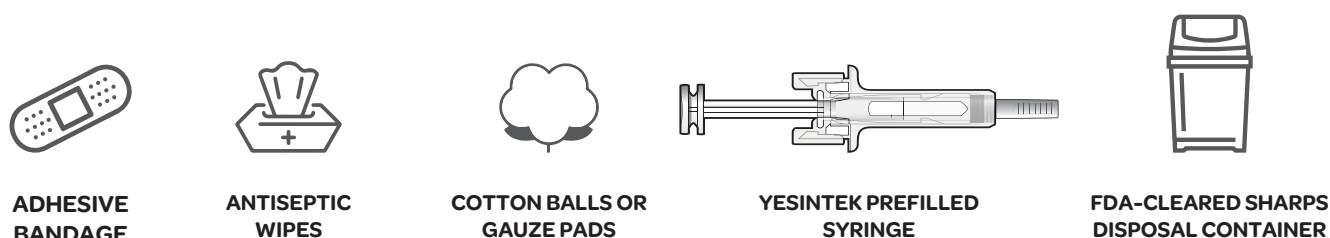
- Store YESINTEK prefilled syringes in a refrigerator between 36°F to 46°F (2°C to 8°C).
- Store YESINTEK in the original carton to protect from light until the time of use.
- Do not freeze YESINTEK.
- Do not shake YESINTEK.
- If needed, individual prefilled syringes may be stored at room temperature up to 86°F (30°C) for a maximum single period of up to 30 days in the original carton to protect from light. Record the date when the prefilled syringe is first removed from the refrigerator on the carton in the space provided. Once a syringe has been stored at room temperature, it should not be returned to the refrigerator. Discard the syringe if not used within 30 days at room temperature storage. Do not use YESINTEK after the expiration date on the carton or on the prefilled syringe.

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

You will need:

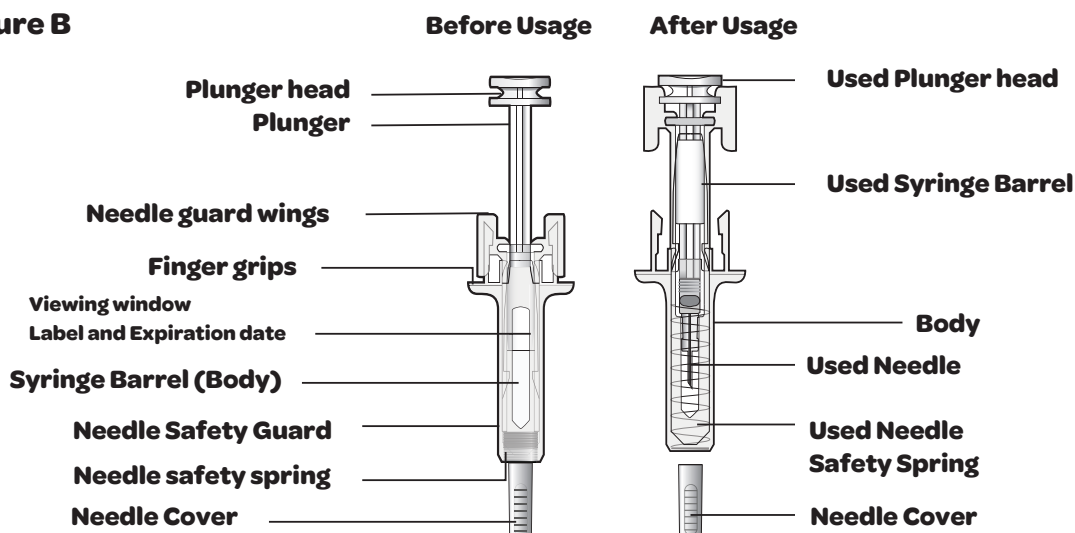
- your prescribed dose of YESINTEK (See Figure B).
- antiseptic wipes.
- cotton balls or gauze pads.
- adhesive bandage.
- FDA-cleared sharps disposal container. **See "Step 4: Dispose of the syringe."**

Figure A



PARTS OF THE PREFILLED SYRINGE

Figure B

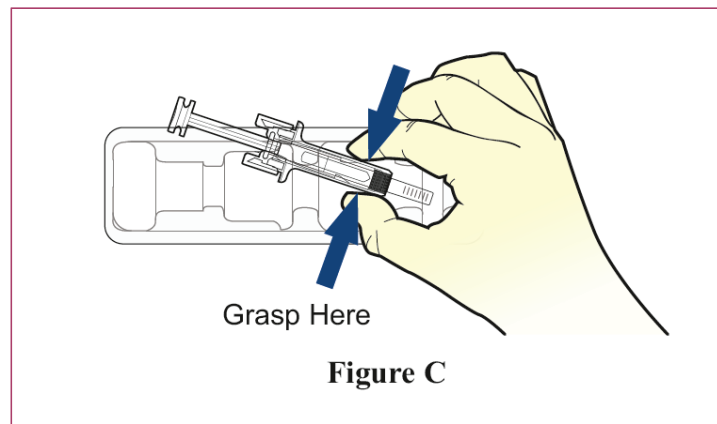


Step 1: Prepare the injection.

- Choose a well-lit, clean, flat work surface.
- Wash your hands well with soap and warm water. Remove prefilled syringe tray from carton.
- Open the tray by peeling away the cover. Hold the prefilled syringe by the Needle safety guard (as shown in the **Figure C**) to remove the prefilled syringe from the tray.

For safety reasons:

- Do not touch or grasp the plunger.
- Do not grasp the gray needle cover.

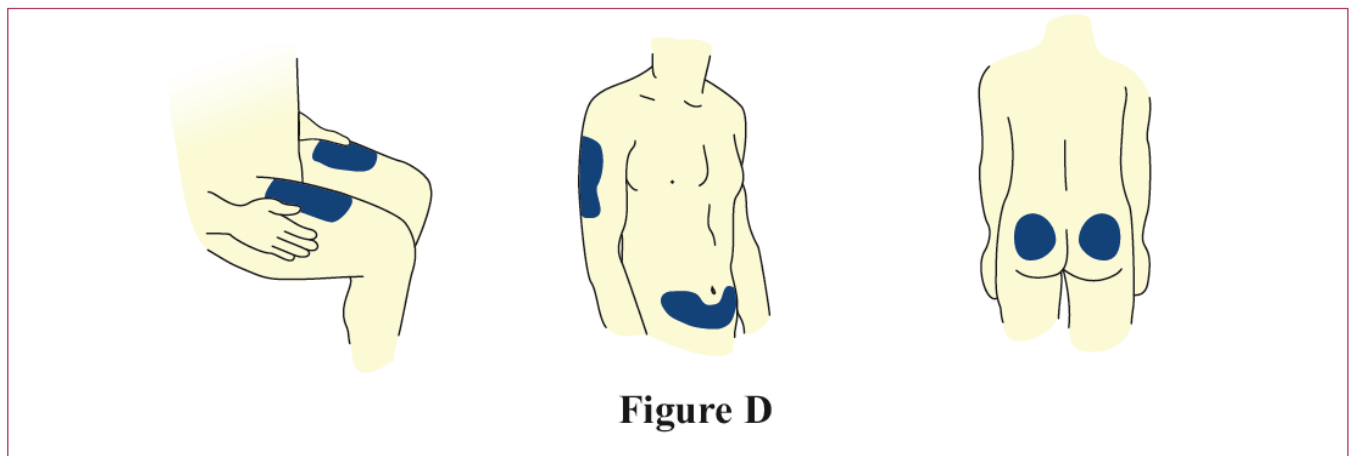


- Hold the prefilled syringe with the covered needle pointing upward.

Step 2: Prepare your injection site

- Choose an injection site around your stomach area (abdomen), buttocks, upper legs (thighs). If a caregiver is giving you the injection, the outer area of the upper arms may also be used. **(See Figure D)***
- **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.

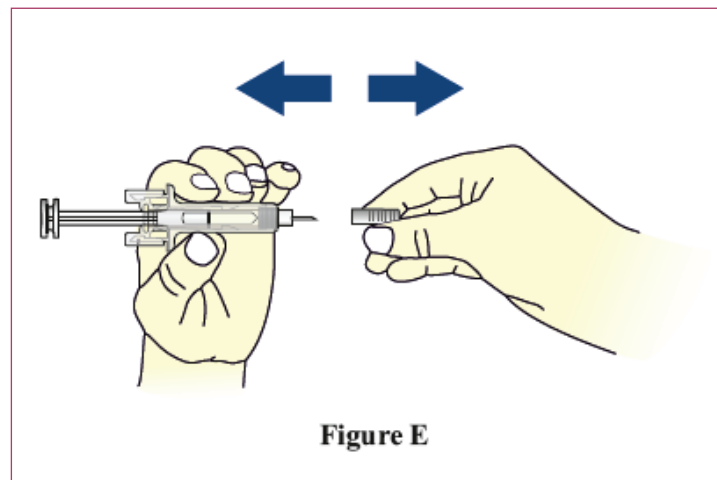


*Areas in blue are recommended injection sites.

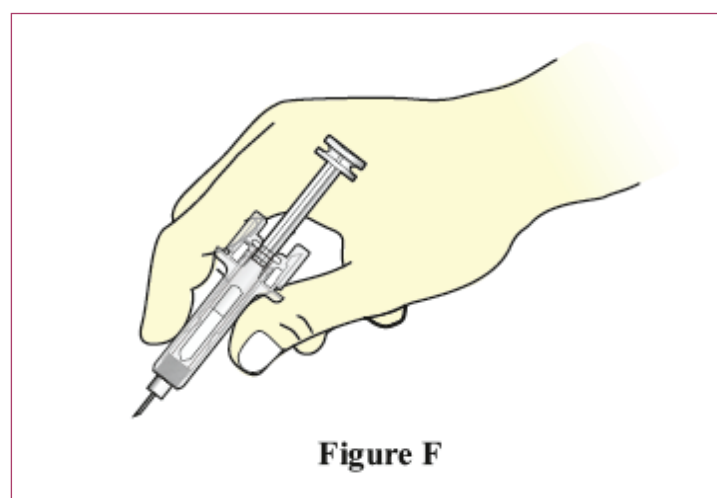
Step 3: Inject YESINTEK

- Remove the needle cover when you are ready to inject your YESINTEK.
- **Do not** touch the plunger while removing the needle cover.
- Hold the body of the prefilled syringe with one hand and pull the needle cover straight off. **(See Figure E)**
- Put the needle cover in the trash.
- You may also see a drop of liquid at the end of the needle. This is normal.

- **Do not** touch the needle or let it touch anything.
- **Do not** use the prefilled syringe if it is dropped without the needle cover in place. Call your doctor, nurse or health professional for instructions.

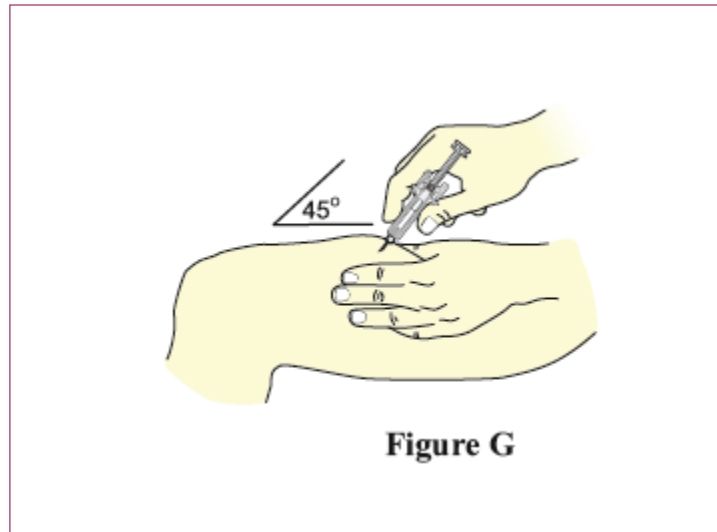


- Hold the body of the prefilled syringe in one hand between the thumb and index fingers. **(See Figure F)**

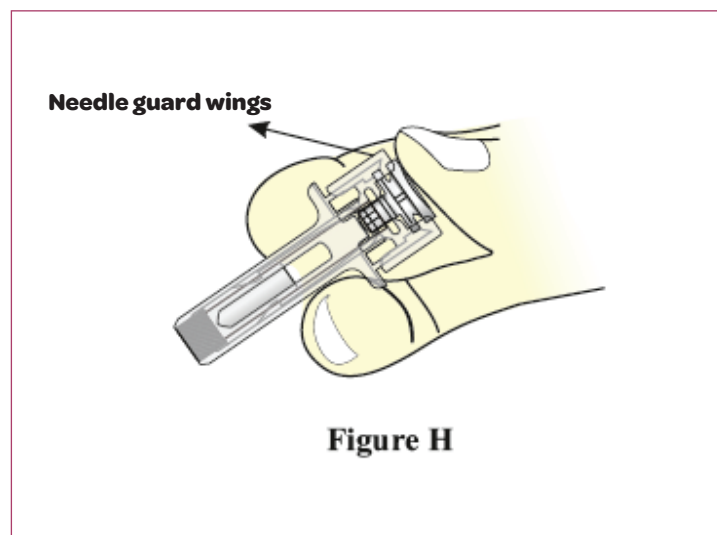


- **Do not** pull back on the plunger at any time.

- 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 G)**



- Inject all of the liquid by using your thumb to push in the plunger until the plunger head is completely between the needle guard wings. **(See Figure H)**



- When the plunger is pushed as far as it will go, keep pressure on the plunger head. Take the needle out of the skin and let go of the skin.
- Slowly take your thumb off the plunger head. This will let the empty syringe move up until the entire needle is covered by the needle guard. **(See Figure I)**

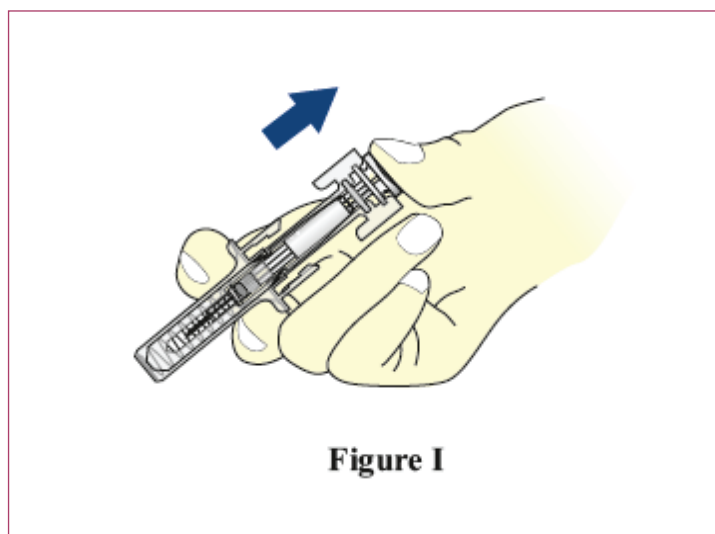


Figure I

- 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 either one 90 mg prefilled syringe or two 45 mg prefilled syringes. If you receive two 45 mg prefilled syringes for a 90 mg dose, you will need to give yourself a second injection right after the first. Repeat Steps 1 to 3 for the second injection using a new syringe. Choose a different site for the second injection.

Step 4: Dispose of the syringe.

- Put the syringe in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose 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 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 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.
- 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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