

**INSTRUCTIONS FOR USE**  
**Ustekinumab (yü-stə-kin-ü-mab)**  
**injection, for subcutaneous use**

**This Instructions for Use contains information on how to inject Ustekinumab using a prefilled syringe.**

**Read this Instructions for Use before you start using Ustekinumab. A healthcare provider should show you how to prepare and give an injection of Ustekinumab the right way.**

If you cannot give the injection:

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

Do not try to inject Ustekinumab until you have been shown how to inject Ustekinumab by a healthcare provider.

**Important information You Need to Know Before Injecting Ustekinumab:**

- **For subcutaneous use only** (inject directly under the skin).
- 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 the healthcare provider.
  - If the dose is 45 mg, you will receive one 45 mg prefilled syringe.
  - If the 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 two injections, one right after the other.**
- 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) or at room temperature for longer than 30 days, call the healthcare provider or pharmacist, or call 1-800-526-7736 for help.
- Make sure the syringe is not damaged.
- **The needle cover on the prefilled syringe contains latex. Do not handle the needle cover on the Ustekinumab prefilled syringe if you are allergic to latex.**
- Check the prefilled syringe for any particles or discoloration. The liquid in the prefilled syringe should look clear and colorless to light yellow with a few small clear or white particles.
- 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 the prefilled syringe may damage the Ustekinumab medicine. If the 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 the injection. Do not pull back on the plunger at any time.

**Storing Ustekinumab prefilled syringes**

- Store Ustekinumab prefilled syringes in the refrigerator between 36 °F to 46 °F (2 °C to 8 °C).
- Store Ustekinumab prefilled syringes in the original carton to protect from light.
- **Do not freeze** Ustekinumab prefilled syringes.

**Ustekinumab**

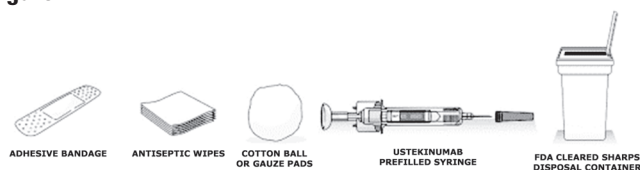
- If needed, Ustekinumab prefilled syringe may be stored at room temperature up to 86 °F (30 °C) for a maximum single period of up to 30 days in the original carton to protect from light.
- Record the date when the prefilled syringe is removed from the refrigerator on the carton in the space provided.
- After a prefilled syringe has been stored at room temperature, do not return it to the refrigerator.
- Throw away (discard) the prefilled syringe if it is not used within 30 days at room temperature storage.

**Keep Ustekinumab and all medicines out of the reach of children. Gather the supplies you will need to prepare and to give the injection. (See Figure A)**

You will need:

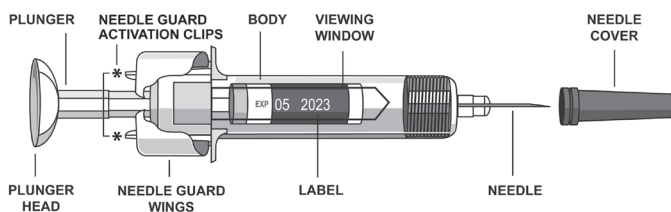
- antiseptic wipes
- cotton balls or gauze pads
- adhesive bandage
- your prescribed dose of Ustekinumab (See Figure B)
- FDA-cleared sharps disposal container. See “Step 4: Disposing of the syringes”

**Figure A**



**Figure B**

**To prevent early activation of the needle safety guard, do not touch the NEEDLE GUARD ACTIVATION CLIPS at any time during use.**



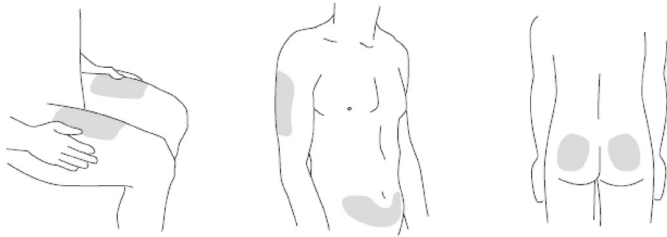
**Step 1: Preparing the injection**

- Choose a well-lit, clean, flat work surface.
- Wash your hands well with soap and warm water.
- Hold the prefilled syringe with the covered needle pointing upward.

**Step 2: Preparing the injection site**

- Choose an injection site around the stomach area (abdomen), buttocks, upper legs (thighs). If a caregiver is giving the injection, the outer area of the upper arms may also be used. (See Figure C)
- **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 the injection.
- **Do not** touch this area again before giving the injection. Let the skin dry before injecting.
- **Do not** fan or blow on the clean area.

Figure C

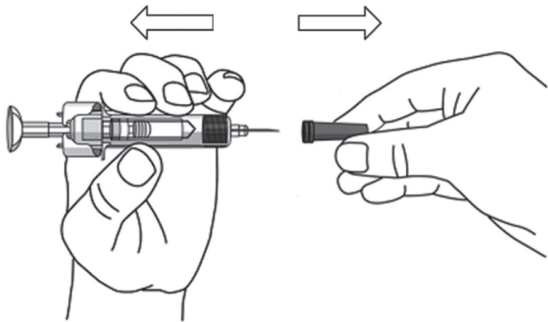


\*Areas in gray are recommended injection sites.

**Step 3: Injecting Ustekinumab**

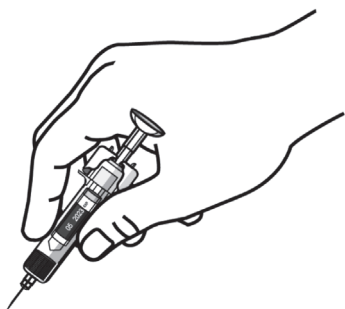
- Remove the needle cover when you are ready to inject Ustekinumab.
- **Do not** touch the plunger or plunger head while removing the needle cover.
- Hold the body of the prefilled syringe with one hand and pull the needle cover straight off. (see Figure D)
- Put the needle cover in the trash.
- You 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.

Figure D



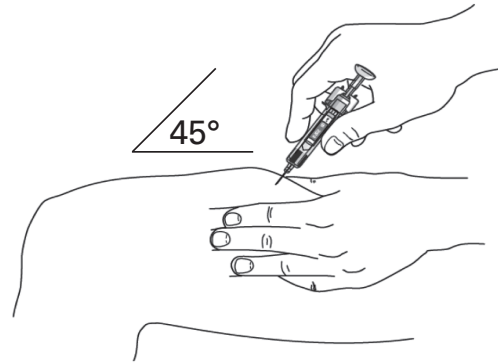
- Hold the body of the prefilled syringe in one hand between the thumb and index fingers. (See Figure E)

Figure E



- **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 F)

Figure F



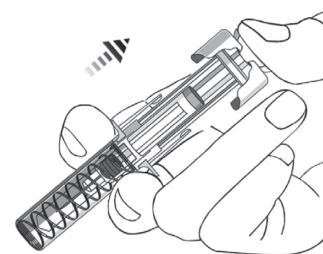
- Inject all of the liquid by using your thumb to push in the plunger until the plunger head is completely between the needle guard wings. (See Figure G)

Figure G



- 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 then 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 H)

Figure H



- When the needle is pulled out of the 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 the 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 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: Disposing of the syringes**

- Put the syringe in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) syringes 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 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 healthcare provider or pharmacist.

Prefilled Syringe Manufactured by:

Janssen Biotech, Inc., Horsham, PA 19044, USA. U.S. License No. 1864 at Baxter Pharmaceutical Solutions, Bloomington, IN 47403 and at Cilag AG, Schaffhausen, Switzerland

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

Revised: 06/2025

**INSTRUCTIONS FOR USE**  
**Ustekinumab (yü-stä-kin-ü-mab)**  
**injection, for subcutaneous use**

This Instructions for Use contains information on how to inject Ustekinumab using a vial.

Read this Instructions for Use before you start using Ustekinumab. A healthcare provider should show you how to prepare, measure the dose, and give an injection of Ustekinumab the right way.

If you cannot give the injection:

- ask your healthcare provider to help you, or
- ask someone who has been trained by a healthcare provider to give the injections.

Do not try to inject Ustekinumab until you have been shown how to inject Ustekinumab by a healthcare provider.

**Important information You Need to Know Before Injecting Ustekinumab:**

- 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 the healthcare provider.
  - If the dose is 45 mg or less you will receive one 45 mg vial.
  - If the dose is 90 mg, you will receive two 45 mg vials **and you will need to give two injections, one right after the other.**
- 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 the healthcare provider or pharmacist, or call 1-800-526-7736 for help.
- Check the vial for any particles or discoloration. The liquid in the vial should look clear and colorless to light yellow with a few small clear or white particles.
- 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 the vial may damage the Ustekinumab medicine. If the vial has been shaken, do not use it. Get a new vial.
- Do not use a Ustekinumab vial more than one time, even if there is medicine left in the vial. After the rubber stopper is punctured, Ustekinumab can become contaminated by harmful bacteria which could cause an infection if re-used. Therefore, throw away any unused Ustekinumab after you give the injection.
- Safely throw away (dispose of) Ustekinumab vials, needles, and syringes after use. See **“Step 6: Disposing of needles, syringes, and vials.”**
- Do not re-use syringes or needles.
- To avoid needle-stick injuries, **do not** recap needles.

**Storing Ustekinumab vials**

- Store Ustekinumab vials in a refrigerator between 36 °F to 46 °F (2 °C to 8 °C).
- Store Ustekinumab vials standing up straight (upright).
- Store Ustekinumab vials in the original carton to protect from light until the time of use.
- **Do not** freeze Ustekinumab vials.

**Keep Ustekinumab and all medicines out of the reach of children.**

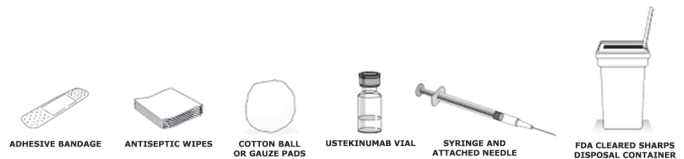
**Gather the supplies you will need to prepare Ustekinumab and to give your injection. (See Figure A)**

You will need:

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

**Ustekinumab**

**Figure A**



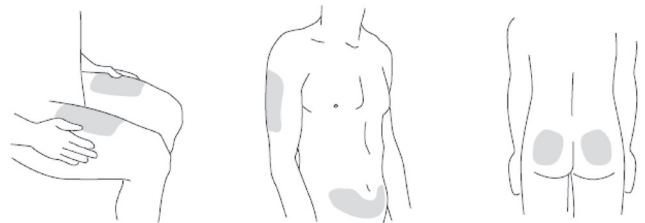
**Step 1: Preparing the injection.**

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

**Step 2: Preparing 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 the injection.
- **Do not** touch this area again before giving the injection. Let the skin dry before injecting.
- **Do not** fan or blow on the clean area.

**Figure B**



\*Areas in gray are recommended injection sites.

**Step 3: Preparing the vial**

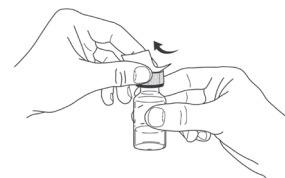
- Remove the cap from the top of the vial. Throw away the cap but do not remove the rubber stopper. (See Figure C)

**Figure C**



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

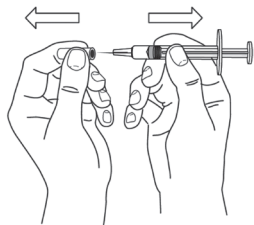
**Figure D**



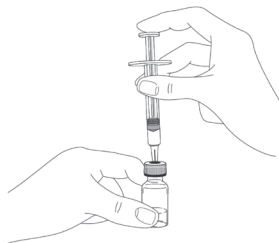
- Do not touch the rubber stopper after you clean it.
- Put the vial on a flat surface.

**Step 4: Preparing the syringe**

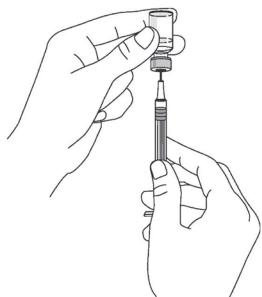
- Pick up the syringe with the needle attached.
- Remove the cap that covers the needle. **(See Figure E)**
- Throw the needle cap away. Do not touch the needle or allow the needle to touch anything.

**Figure E**

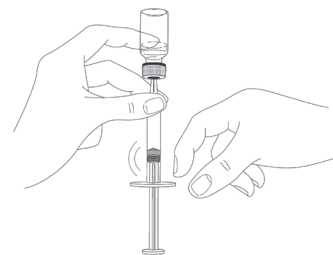
- Carefully pull back on the plunger to the line that matches the dose prescribed by the healthcare provider.
- Hold the vial between your thumb and index (pointer) finger.
- Use your other hand to push the syringe needle through the center of the rubber stopper. **(See Figure F)**

**Figure F**

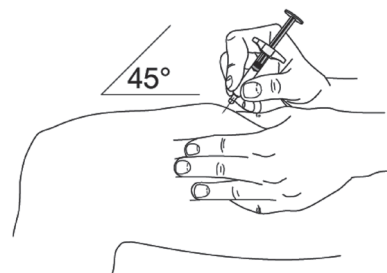
- Push down on the plunger until all of the air has gone from the syringe into the vial.
- Turn the vial and the syringe upside down. **(See Figure G)**
- Hold the Ustekinumab vial with one hand.
- It is important that the needle is always in the liquid in order to prevent air bubbles forming in the 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 the prescribed dose.

**Figure G**

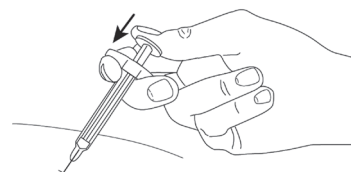
- **Do not remove the needle from the vial.** Hold the syringe with the needle pointing up to see if it has any air bubbles inside.
- If there are air bubbles, gently tap the side of the syringe until the air bubbles rise to the top. **(See Figure H)**
- Slowly press the plunger up until all of the air 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.

**Figure H****Step 5: Injecting Ustekinumab**

- 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)**

**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 the skin and then let go of the skin. **(See Figure J)**

**Figure J**

- When the needle is pulled out of the 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 the dose is 90 mg, you will receive two 45 mg vials and you will need to give a second injection right after the first. Repeat Steps 1 to 5 using a new syringe. Choose a different site for the second injection.**

**Step 6: Disposing of the needles, syringes, and vials**

- **Do not** re-use a syringe or needle.
- To avoid needle-stick injuries, do not recap a needle.
- Put the needles and syringes in an FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) needles and syringes in your household trash.**

## Ustekinumab

---

- If you do not have an 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.
- Throw away the vial into the container where you put the syringes and needles.
- If you have any questions, talk to your healthcare provider or pharmacist.

Vial Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, USA. U.S. License No. 1864 at Cilag AG, Schaffhausen, Switzerland

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

Revised: 06/2025

cp-513635v4