INSTRUCTIONS FOR USE

STELARA® (ustekinumab)
Injection, for subcutaneous use

Instructions for injecting STELARA using a prefilled syringe.

Read this Instructions for Use before you start using STELARA. Your doctor or nurse should show you how to prepare and give your injection of STELARA 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 STELARA yourself until you have been shown how to inject STELARA 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, do not use it. If the expiration date has passed call your doctor or pharmacist, or call 1-800-JANSSEN (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 STELARA prefilled syringe if you are allergic to latex.
- Check your prefilled syringe for any particles or discoloration. Your prefilled syringe should look clear and colorless to light yellow with few 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 your prefilled syringe may damage your STELARA 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.

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

You will need:
- antiseptic wipes
- cotton balls or gauze pads
- adhesive bandage
- your prescribed dose of STELARA (See Figure B)
- FDA-cleared sharps disposal container. See “Step 4: Dispose of the syringe.”
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 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 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 1-3 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 STELARA and all medicines out of the reach of children.

Prefilled Syringe Manufactured by:
Janssen Biotech, Inc., Horsham, PA 19044, US 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: 10/2017

© 2012 Janssen Pharmaceutical Companies 081649-171009
INSTRUCTIONS FOR USE
STELARA® (ustekinumab)
injection, for subcutaneous use

Instructions for injecting STELARA from a vial.

Read this Instructions for Use before you start using STELARA. Your doctor or nurse should show you how to prepare, measure your dose, and give your injection of STELARA 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 STELARA yourself until you have been shown how to inject STELARA 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 1-800-JANSSEN (1-800-526-7736) for help.
• Check the vial for any particles or discoloration. Your vial should look clear and colorless to light yellow with few 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 your vial may damage your STELARA medicine. If your vial has been shaken, do not use it. Get a new vial.
• Do not use a STELARA vial more than one time, even if there is medicine left in the vial. After the cap is punctured, STELARA can become contaminated by harmful bacteria which could cause an infection if re-used. Therefore, throw away any unused STELARA after you give your injection.
• Safely throw away (dispose of) STELARA vials after use.
• Do not recap needles. See “Step 6: Dispose of needles and syringes.”
• To avoid needle-stick injuries, do not recap needles.

Gather the supplies you will need to prepare STELARA and to give your injection. (See Figure A)
You will need:
• a syringe with the needle attached, provided by your pharmacy
• antiseptic wipes
• cotton balls or gauze pads
• adhesive bandage
• your prescribed dose of STELARA
• FDA-cleared sharps disposal container. See “Step 6: Dispose of needles and syringes.”
• Clean the rubber stopper with an antiseptic swab. (See Figure D)

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.

Figure E

• 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)

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 STELARA 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.

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: Inject STELARA
• 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 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 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 doctor or pharmacist.

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

Vial Manufactured by: Janssen Biotech, Inc., Horsham, PA 19044, US License No. 1864 at Cilag AG, Schaffhausen, Switzerland
This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Revised: 10/2017
© 2012, 2016 Janssen Pharmaceutical Companies