Selarsdi®
(ustekinumab-aekn)
Injection • 45mg/0.5mL • 90mg/mL

HOW TO USE THE SELARSDI® PREFILLED SYRINGE

A step-by-step guide to self-injection

This guide is a supplement to the full Instructions for Use. It is not intended to replace the full Instructions for Use. Carefully read the full **Instructions for Use** before using SELARSDI. If you have further questions, ask your healthcare provider.

What is SELARSDI® (ustekinumab-aekn) Injection?

SELARSDI is a prescription medicine used to treat:

- adults and children 6 years of age and older with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light alone or with pills).
- adults and children 6 years of age and older with active psoriatic arthritis.
- adults with moderately to severely active Crohn's disease.
- adults with moderately to severely active ulcerative colitis.

It is not known if SELARSDI is safe and effective in children with Crohn's disease or ulcerative colitis or in children less than 6 years of age with plaque psoriasis or psoriatic arthritis.

Please see additional Important Safety Information on pages 9-10 and click here for full Prescribing Information and Medication Guide for SELARSDI.

teva Biosimilars

This guide provides a basic outline of SELARSDI® self-injection. Once your healthcare provider has shown you how to prepare and inject SELARSDI and decided you are ready to self-inject, it can help give you the confidence you need to take SELARSDI in the comfort of your home.

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

GATHER YOUR ITEMS

Take your carton of SELARSDI out of the fridge

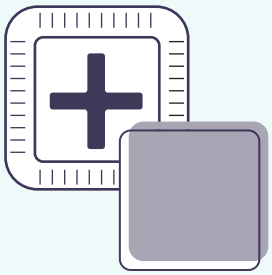
If needed, you may keep SELARSDI at room temperature for up to 30 days before using it. Once you've stored it at room temperature, do not return it to the fridge.

- **Do not** use SELARSDI if it has been kept at room temperature for more than 30 days or stored above 86°F (30°C)

Check both the **dose** and the **expiration date** printed on the carton.

- SELARSDI comes in 2 strengths: 45 milligrams and 90 milligrams. Your healthcare provider will have prescribed the right dose for you
- **Do not** use SELARSDI if the expiration date has passed. Call your healthcare provider, pharmacist, or Teva Pharmaceuticals at 1-888-483-8279 for help

Gather the other supplies you will need



Antiseptic wipe

Cotton ball or gauze pad

Adhesive bandage

FDA-cleared sharps disposal container

These supplies are not included with your medicine.

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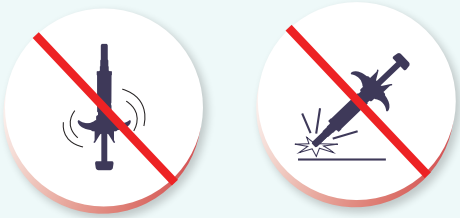
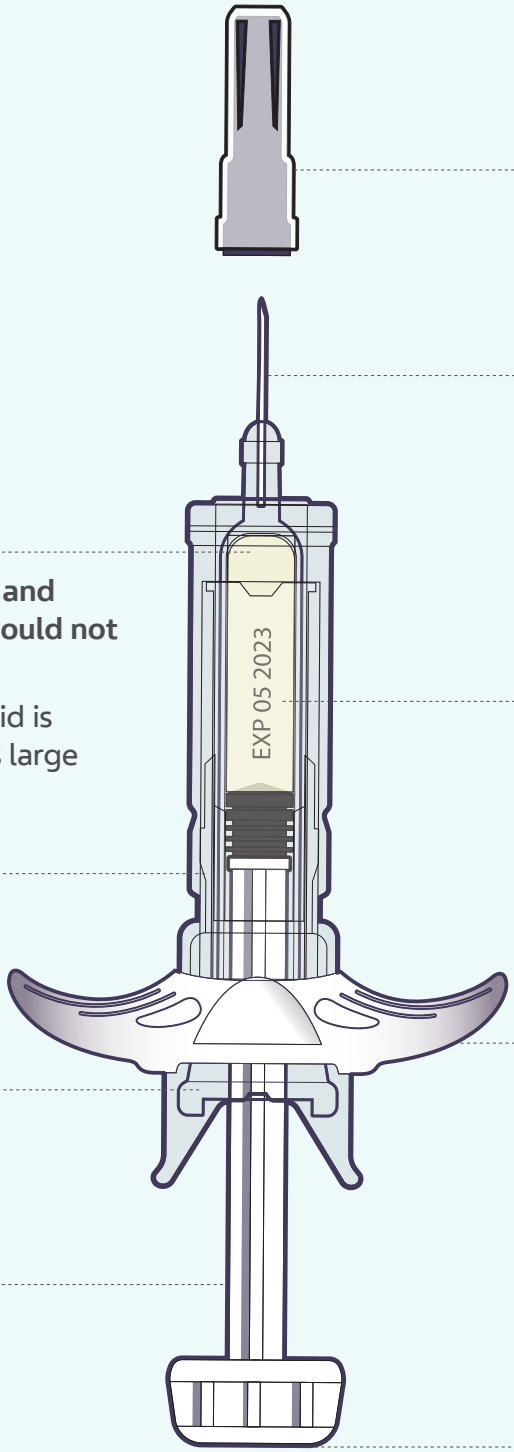
Inspect the SELARSDI® prefilled syringe

Make sure you take note of all the different parts of the syringe.



Do not shake or drop your SELARSDI carton or syringe.



NEEDLE COVER

NEEDLE

LABEL

NEEDLE GUARD WINGS

PLUNGER HEAD

VIEWING WINDOW

The liquid inside should look **clear and colorless to slightly yellow and should not have any particles**.

- **Do not** use the syringe if the liquid is frozen, discolored, cloudy, or has large particles. Get a new syringe

BODY

NEEDLE GUARD ACTIVATION CLIPS

PLUNGER

For subcutaneous injection only.

Check the **dose** and **expiration date** printed on the syringe, and check your syringe for any damage. A damaged syringe should never be used.

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PREPARE TO INJECT

Wash hands thoroughly

Use soap and warm water.

Choose a place on your body to inject SELARSDI®

You can choose the stomach area—avoiding a 2-inch circle around the belly button—the upper thighs, or buttocks.

- If someone else is giving the injection, they may also use the outer area of the upper arms

Do not inject:

- Through clothes
- Into skin that is tender, bruised, red, or hard

Clean the area with an antiseptic wipe and let your skin dry naturally

Do not fan, blow on, or touch the cleaned area.

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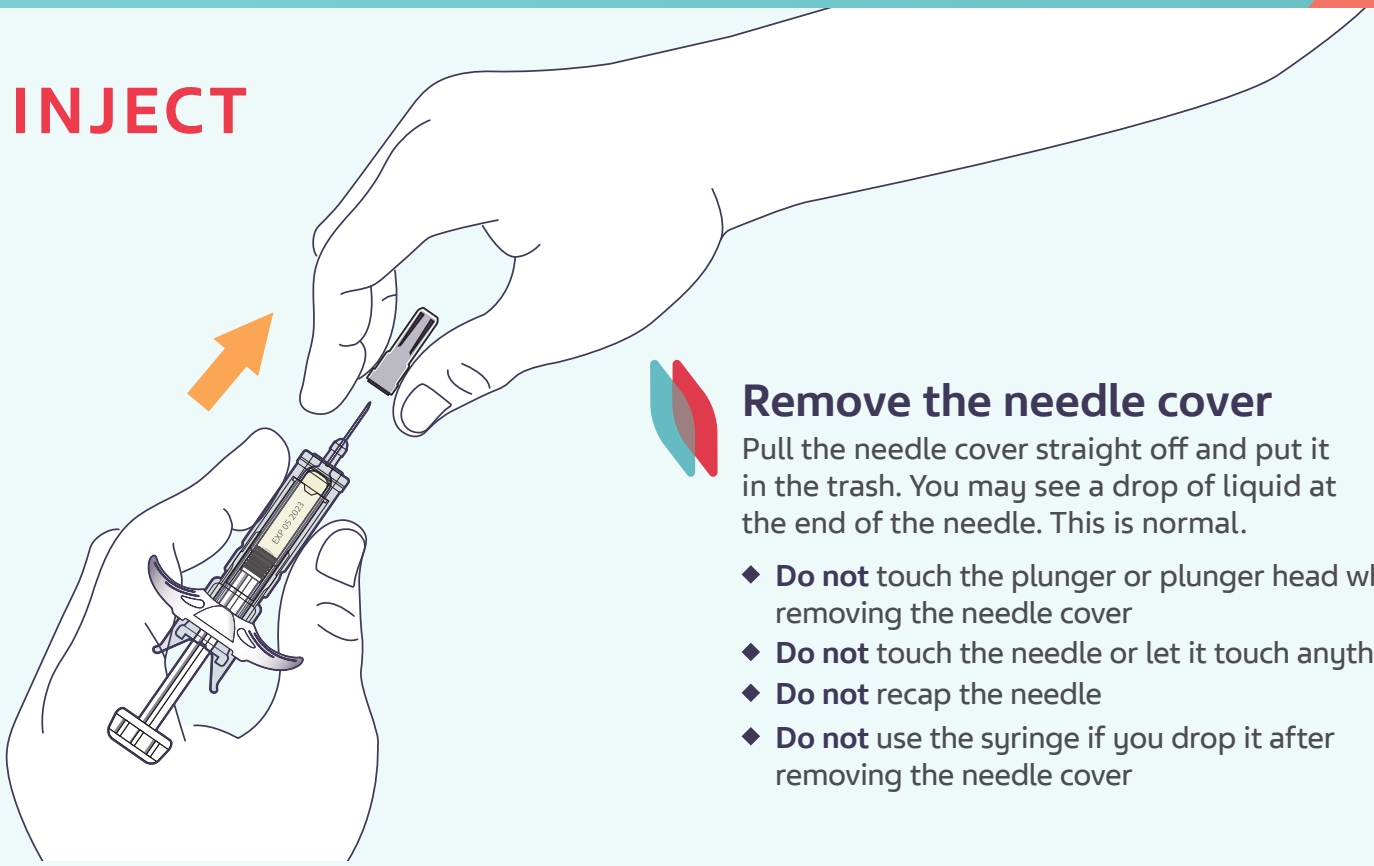
INJECT



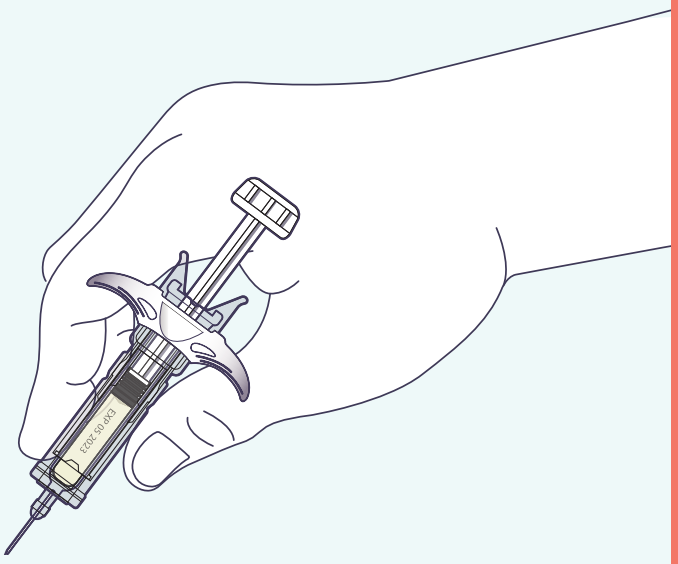
Remove the needle cover

Pull the needle cover straight off and put it in the trash. You may see a drop of liquid at the end of the needle. This is normal.

- **Do not** touch the plunger or plunger head while removing the needle cover
- **Do not** touch the needle or let it touch anything
- **Do not** recap the needle
- **Do not** use the syringe if you drop it after removing the needle cover

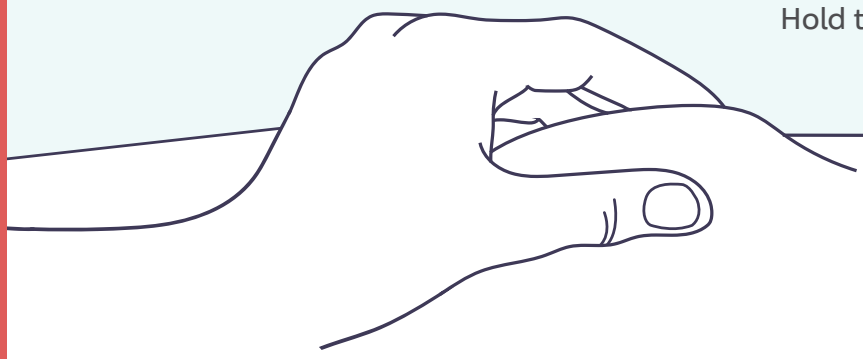
Hold the syringe with one hand

Hold the body of the syringe between the thumb and index finger.



With the other hand, gently pinch the clean and dry area of skin

Hold the skin firmly.



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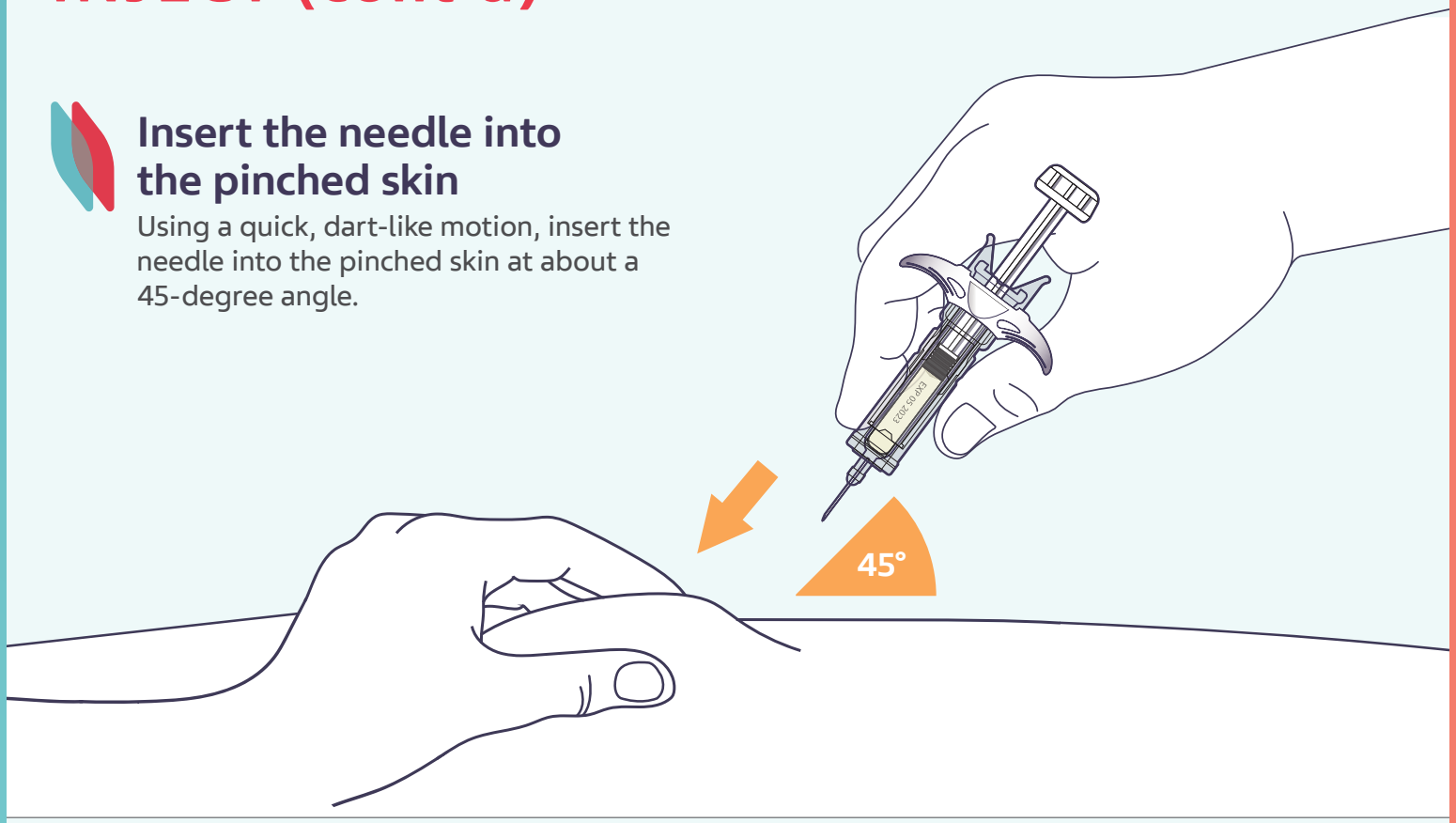
INJECT (cont'd)

Insert the needle into the pinched skin

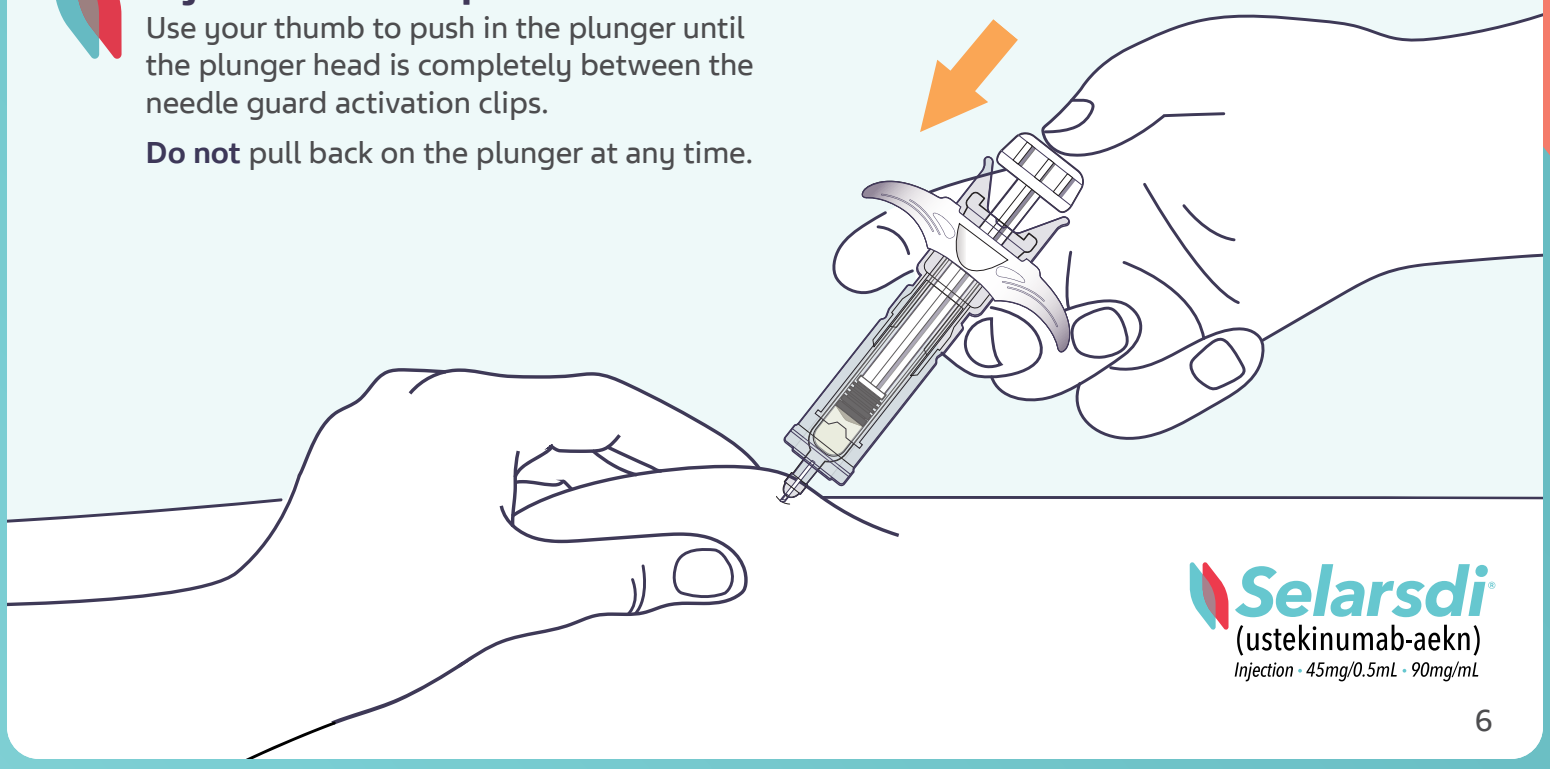
Using a quick, dart-like motion, insert the needle into the pinched skin at about a 45-degree angle.



Inject all the liquid

Use your thumb to push in the plunger until the plunger head is completely between the needle guard activation clips.

Do not pull back on the plunger at any time.



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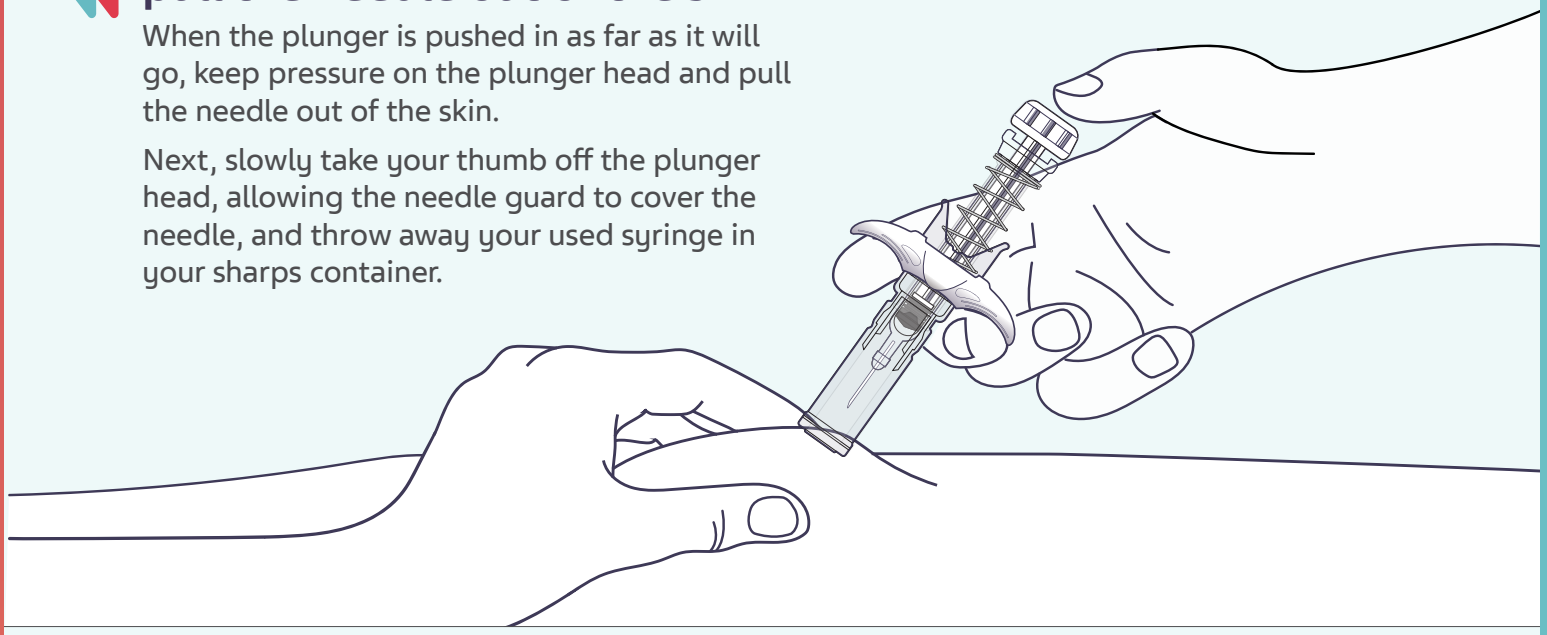
FINISH INJECTING

Keeping pressure on the plunger head, pull the needle out of the skin

When the plunger is pushed in as far as it will go, keep pressure on the plunger head and pull the needle out of the skin.

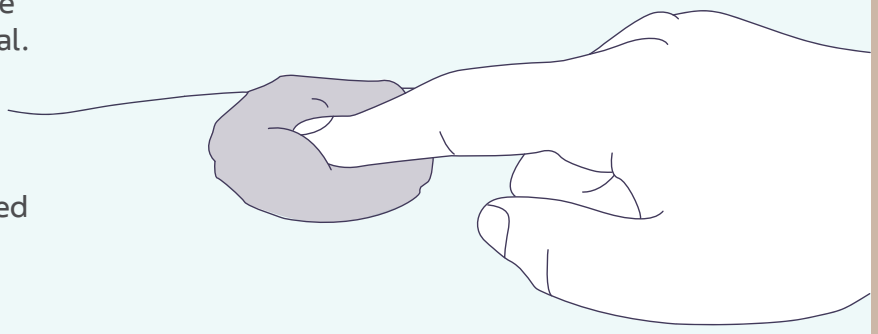
Next, slowly take your thumb off the plunger head, allowing the needle guard to cover the needle, and throw away your used syringe in your sharps container.



Treat the injection site

You may see a little bleeding where the needle went into the skin. This is normal. You can press a cotton ball or gauze pad onto the area and apply a small adhesive bandage, if necessary.

- **Do not** rub the skin where you injected



INJECTION COMPLETE!

If your prescribed dose is **90 mg** and you have **two 45 mg** prefilled syringes, you will need to give a second injection right after the first.

Use a different site for each injection.

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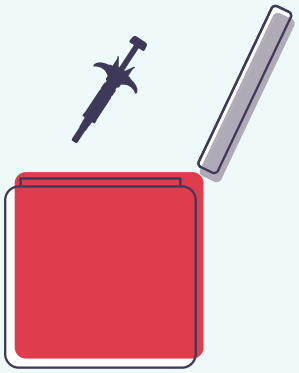
DISPOSE OF SYRINGE

Throw away your used syringes the right way



Put used syringes in an FDA-cleared sharps container immediately after use.

If you don't have an FDA-cleared sharps disposal container, you may be able to use an appropriate household container.

An appropriate household container:

- Is made of heavy-duty plastic
- Can be closed with a tight-fitting, puncture-resistant lid
- Stays upright and stable during use
- Is leak-resistant
- Is properly labeled to warn of hazardous waste inside

Tape the container shut when it is close to full.

When your container is almost full, follow your community guidelines for the right way to dispose of it

Do not use your household trash for used syringes or—unless your community allows it—for your sharps container.

Do not recycle your sharps disposal container.

CONGRATULATIONS!

If you've familiarized yourself with these steps and read the full Instructions for Use, you now know what you need to know about self-injecting SELARSDI®.

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IMPORTANT SAFETY INFORMATION

SELARSDI® (ustekinumab-aekn) Injection is a prescription medicine that affects your immune system. SELARSDI can increase your chance of having serious side effects including:

Serious Infections

SELARSDI may lower your ability to fight infections and may increase your risk of infections. While taking ustekinumab products, some people have serious infections, that may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

- Your healthcare provider should check you for TB before starting SELARSDI and watch you closely for signs and symptoms of TB during treatment with SELARSDI.
- If your healthcare provider feels that you are at risk for TB, you may be treated for TB before and during treatment with SELARSDI.
- Your healthcare provider should watch you closely for signs and symptoms of TB while you are being treated with SELARSDI.

You should not start taking SELARSDI if you have any kind of infection unless your healthcare provider says it is okay.

Before starting SELARSDI, tell your healthcare provider if you:

- think you have an infection or have symptoms of an infection such as:
  - fever, sweats, or chills
  - muscle aches
  - cough
  - shortness of breath
  - blood in phlegm
  - weight loss
  - warm, red, or painful skin or sores on your body
  - diarrhea or stomach pain
  - burning when you urinate or urinate more often than normal
  - feel very tired
- are being treated for an infection or have any open cuts.
- get a lot of infections or have infections that keep coming back.
- have TB, or have been in close contact with someone with TB.

After starting SELARSDI, call your healthcare provider right away if you have any symptoms of an infection (see above). These may be signs of infections such as chest infections, or skin infections or shingles that could have serious complications. SELARSDI can make you more likely to get infections or make an infection that you have worse. People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for certain serious infections that can spread throughout the body and cause death. People who take SELARSDI may also be more likely to get these infections.

Cancers

SELARSDI may decrease the activity of your immune system and increase your risk for certain types of cancers. Tell your healthcare provider if you have ever had any type of cancers. Some people who had risk factors for skin cancer developed certain types of skin cancers while receiving ustekinumab products. During your treatment with SELARSDI, tell your healthcare provider if you have any new skin growths.

Serious Allergic Reactions

Serious allergic reactions can occur. Stop using SELARSDI and get medical help right away if you have any symptoms of a serious allergic reaction such as: feeling faint, swelling of your face, eyelids, tongue or throat, chest tightness, or skin rash.

Please see additional Important Safety Information on page 1 and page 10 and click here for full Prescribing Information and Medication Guide for SELARSDI.

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IMPORTANT SAFETY INFORMATION (cont'd)

Lung Inflammation

Cases of lung inflammation have happened in some people who receive ustekinumab products and may be serious. These lung problems may need to be treated in a hospital. Tell your doctor right away if you develop shortness of breath or a cough that doesn't go away during treatment with SELARSDI.

Before you use or receive SELARSDI, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section "What is the most important information I should know about SELARSDI?"
- ever had an allergic reaction to ustekinumab products or any of the ingredients in SELARSDI. Ask your doctor if you are not sure.
- have recently received or are scheduled to receive an immunization (vaccine). People who are being treated with SELARSDI should avoid receiving live vaccines. Tell your healthcare provider if anyone in your house needs a live vaccine. The viruses used in some types of live vaccines can spread to people with a weakened immune system and can cause serious problems. **You should avoid receiving the BCG vaccine during the one year before receiving SELARSDI or one year after you stop receiving SELARSDI.**
- have any new or changing lesions within psoriasis areas or on normal skin.
- are receiving or have received allergy shots, especially for serious allergic reactions. Allergy shots may not work as well for you during treatment with SELARSDI. SELARSDI may also increase your risk of having an allergic reaction to an allergy shot.
- receive or have received phototherapy for your psoriasis.
- are pregnant or plan to become pregnant. It is not known if SELARSDI can harm your unborn baby. You and your healthcare provider should decide if you will receive SELARSDI.
- are breastfeeding or plan to breastfeed. SELARSDI can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive SELARSDI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

When prescribed SELARSDI:

- Use SELARSDI exactly as your healthcare provider tells you to. The healthcare provider will determine the right dose of SELARSDI, the amount for each injection, and how often it should be given. Be sure to keep all scheduled follow-up appointments.
- SELARSDI is intended for use under the guidance and supervision of your healthcare provider. In children it is recommended that SELARSDI be administered by a healthcare provider. If a healthcare provider decides that you or a caregiver may give your injections of SELARSDI at home, you or a caregiver should receive training on the right way to prepare and inject SELARSDI. Do not try to inject SELARSDI until you have been shown how to inject SELARSDI by a healthcare provider.

Common side effects of SELARSDI include: nasal congestion, sore throat, and runny nose, upper respiratory infections, fever, headache, tiredness, itching, nausea and vomiting, influenza, redness at the injection site, vaginal yeast infections, urinary tract infections, sinus infection, bronchitis, diarrhea, stomach pain and joint pain.

These are not all of the possible side effects with SELARSDI. Call your doctor for medical advice about side effects. Ask your doctor or pharmacist for more information.

To report SUSPECTED ADVERSE REACTIONS, contact Teva Pharmaceuticals at 1-888-483-8279 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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