

PATIENT INFORMATION LEAFLET

SKYRIZI SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE 150mg/mL

SKYRIZI SOLUTION FOR INJECTION IN PRE-FILLED PEN 150mg/mL

(risankizumab)

Read all of this leaflet carefully before you start using this medicine. It includes important information on the safe and effective use of this medicine.

1. WHAT SKYRIZI IS USED FOR

SKYRIZI is used to treat:

- moderate to severe plaque psoriasis in adults.
- active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to at least one prior disease-modifying anti-rheumatic drug (DMARD) therapy.

2. HOW SKYRIZI WORKS

SKYRIZI contains risankizumab. It works by stopping a protein in the body called IL-23, which causes inflammation.

Plaque Psoriasis

SKYRIZI reduces inflammation and can therefore help to improve skin clearance and the appearance of nails. It also reduces symptoms of plaque psoriasis such as burning, itching, pain, redness, and scaling.

Psoriatic Arthritis

SKYRIZI reduces the inflammation and can therefore help to reduce pain, stiffness, and swelling in and around your joints, pain and stiffness in your spine, psoriatic skin rash, psoriatic nail damage, and it may limit damage to the bone and cartilage in your joints. These effects can ease your normal daily activities, reduce tiredness, and improve your quality of life.

3. WHAT SKYRIZI CONTAINS

Each 150 mg/mL prefilled pen or prefilled syringe contains 150 mg of the active ingredient, risankizumab, in 1 mL of solution.

The other ingredients in the 150 mg/mL prefilled pen or prefilled syringe are sodium acetate trihydrate, acetic acid, trehalose dihydrate, polysorbate 20 and water for injection.

Information about certain ingredients in SKYRIZI

SKYRIZI 150 mg/mL contain less than 1 mmol sodium (23 mg) per 150 mg dose, i.e., essentially 'sodium-free'.

4. DOSAGE FORM/APPEARANCE

SKYRIZI 150 mg/mL is a clear and colorless to yellow liquid in a prefilled pen or a prefilled syringe with needle guard.

Each carton contains 1 prefilled pen or 1 prefilled syringe.

5. WHAT YOU NEED TO KNOW BEFORE YOU USE SKYRIZI

Do not take SKYRIZI if:

- you have had a serious allergic reaction to risankizumab or any of the other ingredients of SKYRIZI (listed in section 3). Symptoms of serious allergic reactions include: trouble breathing, feeling faint or dizzy, swelling of the face, lips, tongue, or throat, difficulty swallowing or severe itching of the skin, with a red rash or raised bumps.
- any of these symptoms occur during treatment with SKYRIZI, stop taking SKYRIZI and get emergency medical help right away.
- you have an infection, including active tuberculosis, which your doctor thinks is important

Talk to your doctor, pharmacist or nurse before and during use of SKYRIZI if:

- you currently have an infection or if you have an infection that keeps coming back.
- you have tuberculosis (TB).
- you have recently received or plan to receive an immunization (vaccine). You should not be given certain types of vaccines while using SKYRIZI.

Children and adolescents

SKYRIZI is not recommended for children and adolescents under 18 years of age. This is because SKYRIZI has not been studied in this age group.

Taking other medicines with SKYRIZI

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines, or if you have recently had or are going to have a vaccination. You should not be given certain types of vaccines while using SKYRIZI.

Pregnancy and breastfeeding with SKYRIZI

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This is because it is not known how this medicine will affect the baby.

If you are a woman of childbearing potential, you should use contraception while using SKYRIZI and for at least 20 weeks after your last dose of SKYRIZI.

Breastfeeding

If you are breastfeeding or are planning to breastfeed, talk to your doctor before using this medicine.

Driving and using machines with SKYRIZI

SKYRIZI is not likely to affect your driving and use of machines.

6. POSSIBLE SIDE EFFECTS WITH SKYRIZI

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Talk to your doctor or get medical help immediately if you have symptoms of serious infection such as:

- fever, flu-like symptoms, night sweats
- feeling tired or short of breath, cough which will not go away
- warm, red and painful skin, or a painful skin rash with blisters

Your doctor will decide if you can keep using SKYRIZI.

Other side effects

Tell your doctor, pharmacist or nurse if you get any of the following side effects:

Very common: may affect more than 1 in 10 people

- upper respiratory infections with symptoms such as sore throat and stuffy nose

Common: may affect up to 1 in 10 people

- feeling tired
- fungal skin infection
- injection site reactions
- headache

Uncommon: may affect up to 1 in 100 people

- small raised red bumps on the skin

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

7. HOW TO USE SKYRIZI

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure how to use this medicine.

SKYRIZI 150 mg/mL prefilled syringe and prefilled pen is injected under your skin (called ‘subcutaneous injection’).

You and your doctor, pharmacist or nurse will decide if you should inject SKYRIZI yourself. Do not inject yourself with this medicine unless you have been trained by your doctor, pharmacist or nurse. A caregiver may also give your injections after training.

Read the ‘Instructions for Use’ before injecting SKYRIZI yourself.

How much SKYRIZI to use

Plaque Psoriasis and Psoriatic Arthritis

The dose is 150 mg. After the first dose, you will have the next dose 4 weeks later, and then every 12 weeks.

If using the 150 mg/mL prefilled pen or prefilled syringe, each dose is given as one 150 mg injection.

If you use too much SKYRIZI

If you have used more SKYRIZI than you should or the dose has been given sooner than prescribed, talk to your doctor.

If you forget to use SKYRIZI

If you forget to use SKYRIZI, inject a dose as soon as you remember. Talk to your doctor if you are not sure what to do.

If you stop using SKYRIZI

Do not stop using SKYRIZI without talking to your doctor first. If you stop treatment, your symptoms may come back.

8. HOW TO STORE SKYRIZI

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiration date which is stated on the pen or syringe label and outer carton after 'EXP'.

Store in a refrigerator at 2 °C – 8 °C. Do not freeze.

Keep in the original carton in order to protect from light.

If needed, you may also store SKYRIZI 150 mg/mL pen or prefilled syringe out of the refrigerator (up to a maximum of 25°C (77°F)) for up to 24 hours in the original carton to protect from light.

SKYRIZI 150 mg/mL liquid should look clear to yellow.

The liquid may contain tiny white or clear particles. Do not use if liquid is cloudy or contains flakes or large particles.

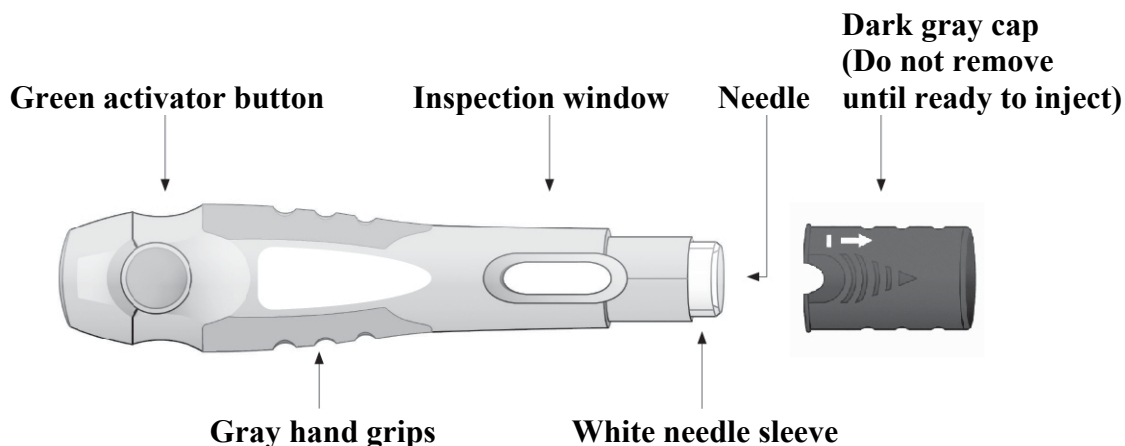
Ask your doctor, pharmacist or nurse how to throw away used pens or syringes safely.

9. INSTRUCTIONS FOR USE

SKYRIZI 150 MG/ML PREFILLED PEN

Please read complete instructions before using SKYRIZI

SKYRIZI prefilled pen

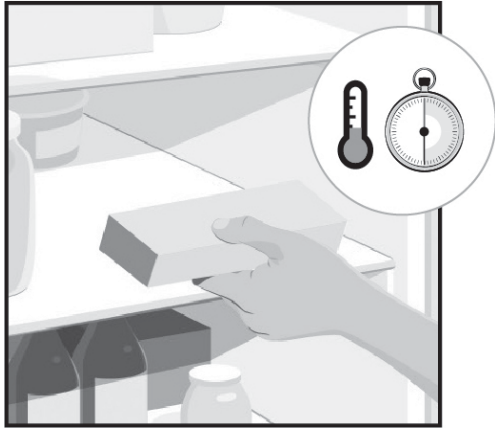


Important information to know before you inject SKYRIZI

- Receive training on how to inject SKYRIZI before giving an injection. Talk to your doctor, pharmacist or nurse if you need help
- Mark the dates on your calendar so you know when to next use SKYRIZI
- Keep SKYRIZI in the original carton to protect from light until it is time to use it
- Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **30 to 90 minutes** before injecting
- **Do not** inject if the liquid in the inspection window is cloudy or contains flakes or large particles. The liquid should look clear to yellow and may contain tiny white or clear particles
- **Do not** use if expiration date (EXP) has passed
- **Do not** use if liquid has been frozen (even if thawed)
- **Do not** shake the pen
- **Do not** use if pen has been dropped or damaged
- **Do not** use if the carton perforations are broken. Return this medicine to the pharmacy
- **Do not** remove the dark gray cap until just before the injection

Follow the steps below each time you use SKYRIZI

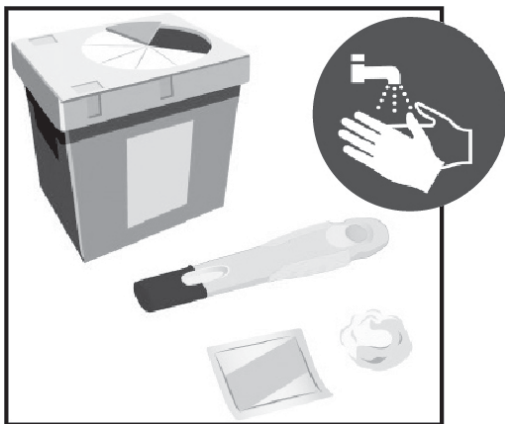
STEP 1



Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **30 to 90 minutes** before injecting.

- **Do not** remove the pen from the carton while allowing SKYRIZI to reach room temperature
- **Do not** warm SKYRIZI in any other way. For example, **do not** warm it in a microwave or in hot water
- **Do not** use the pen if liquid has been frozen, even if it has been thawed

STEP 2



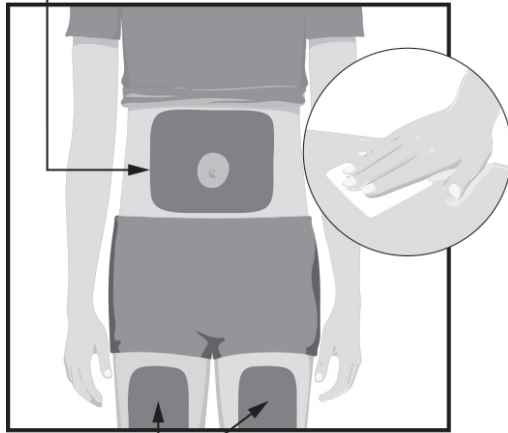
Place the following on a clean, flat surface:

- 1 prefilled pen
- 1 alcohol pad
- 1 cotton ball or gauze pad
- special disposal container

Wash and dry your hands.

STEP 3

Areas to inject



Areas to inject

Choose from these 3 areas to inject:

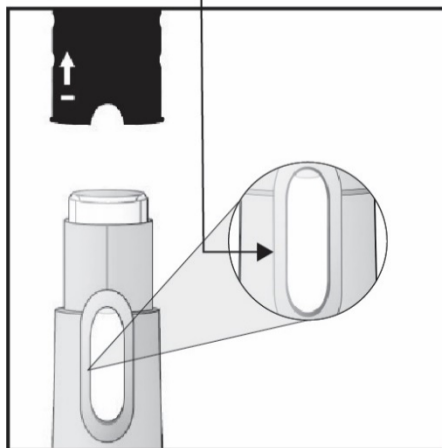
- front of left thigh
- front of right thigh
- belly (abdomen) at least 5 cm from the belly button (navel)

Before the injection, wipe where you will inject in a circular motion with an alcohol pad.

- **Do not** touch or blow on the injection site after it is cleaned. Allow the skin to dry before injecting
- **Do not** inject through clothes
- **Do not** inject into skin that is sore, bruised, red, hard, scarred, or has stretch marks
- **Do not** inject into areas affected by psoriasis

STEP 4

Check liquid



Hold the pen with the dark gray cap pointing up, as shown.

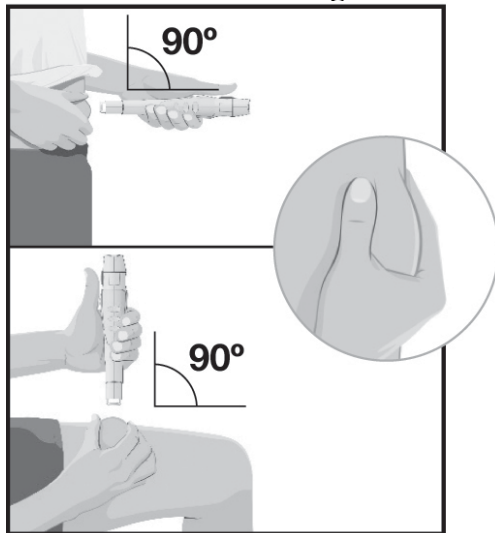
- Pull the dark gray cap straight off
- Throw the dark gray cap away

Check the liquid through the inspection window.

- It is normal to see bubbles in the liquid
- The liquid should look clear to yellow and may contain tiny white or clear particles
- **Do not** use if the liquid is cloudy or contains flakes or large particles

STEP 5

Abdomen or Thigh



Hold the pen with your fingers on the gray hand grips.

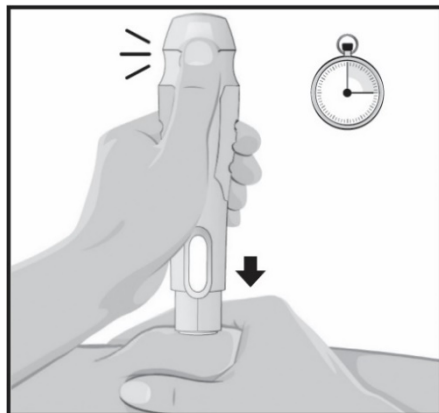
Turn the pen so that the white needle sleeve points toward the injection site and you can see the green activator button.

Gently squeeze the skin at your injection site to make a raised area and hold it firmly.

Place the white needle sleeve straight (90° angle) against the raised injection site.

STEP 6

First “click” 15 seconds



Hold the pen so that you can see the green activator button and inspection window.

Push and keep pressing the pen down against the raised injection site.

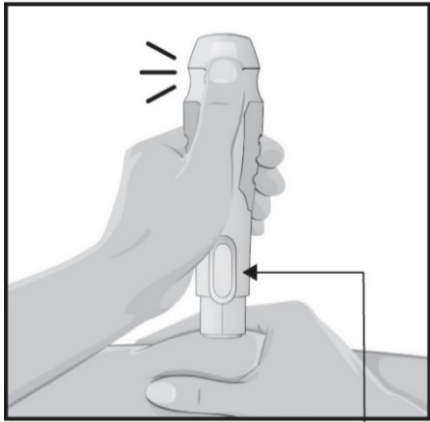
- The pen will activate only if the white needle sleeve is pressed down against the injection site before pressing the green activator button

Press the green activator button and hold the pen for **15** seconds.

- A loud “click” means the start of the injection

STEP 7

Second “click”



Yellow indicator

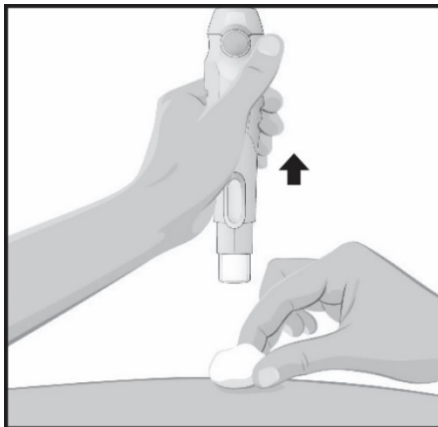
Keep pressing the pen down against the injection site.

The injection is complete when:

- the pen has made a second “click” **or**
- the yellow indicator has filled the inspection window

This takes **up to 15** seconds.

STEP 8



When the injection is complete, slowly pull the pen out from the skin.

The white needle sleeve will cover the needle tip and make another “click.”

After completing the injection, place a cotton ball or gauze pad on the skin at the injection site.

- **Do not** rub the injection site
- Slight bleeding at the injection site is normal

STEP 9



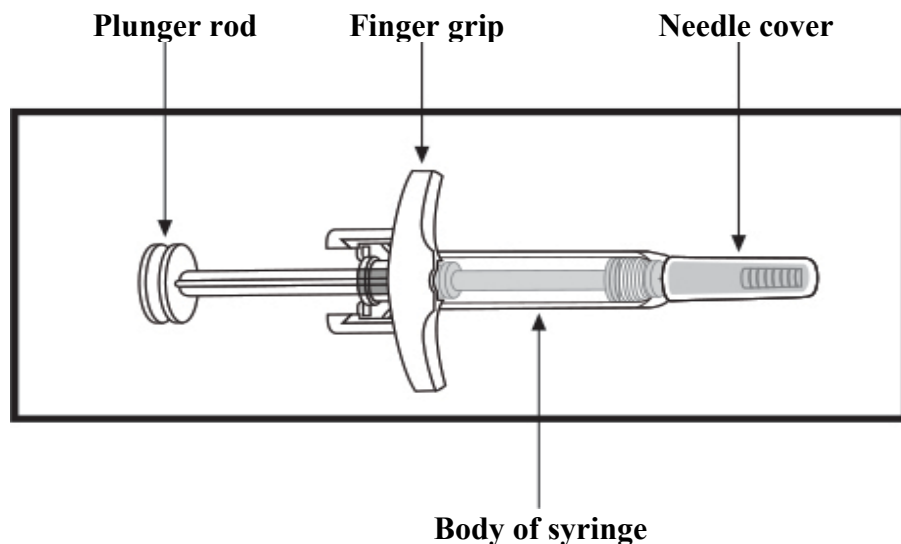
Throw away the used pen in a special disposal container right away after use.

- **Do not** throw away the used pen in the household waste
- Your doctor, pharmacist or nurse will tell you how to return the full special disposal container

SKYRIZI 150 MG/ML PREFILLED SYRINGE

Please read complete instructions before using SKYRIZI

SKYRIZI prefilled syringe



Important information to know before you inject SKYRIZI

- Receive training on how to inject SKYRIZI before giving an injection. Talk to your doctor, pharmacist or nurse if you need help
- Mark the dates on your calendar so you know when to next use SKYRIZI
- Keep SKYRIZI in the original carton to protect from light until it is time to use it
- **Do not** inject if the liquid is cloudy or contains flakes or large particles. The liquid should look clear to yellow and may contain tiny white or clear particles
- **Do not** use if expiration date (EXP) has passed
- **Do not** use if liquid has been frozen (even if thawed)
- **Do not** shake the syringe
- **Do not** use if syringe has been dropped or damaged
- **Do not** use if the carton perforations are broken. Return this medicine to the pharmacy
- **Do not** remove the needle cover until just before the injection

For a more comfortable injection: Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **15 to 30 minutes** before injecting.

- **Do not** remove the syringe from the carton until ready to inject
- **Do not** warm SKYRIZI in any other way. For example, **do not** warm it in a microwave or in hot water

Follow the steps below each time you use SKYRIZI

STEP 1



Remove the prefilled syringe from cardboard sleeve by holding the finger grip.

- **Do not** hold or pull plunger rod when removing the prefilled syringe from the sleeve

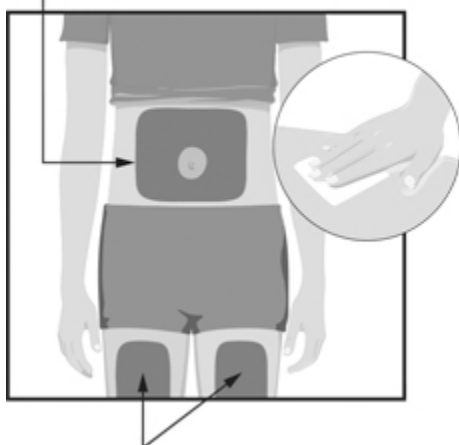
Place the following on a clean, flat surface:

- 1 prefilled syringe
- 1 alcohol pad
- 1 cotton ball or gauze pad
- special disposal container

Wash and dry your hands.

STEP 2

Areas to inject



Areas to inject

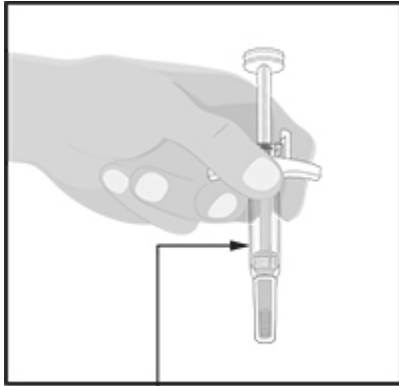
Choose from these 3 areas to inject:

- front of left thigh
- front of right thigh
- belly (abdomen) at least 5 cm from the belly button (navel)

Before the injection, wipe where you will inject in a circular motion with an alcohol pad.

- **Do not** touch or blow on the injection site after it is cleaned. Allow the skin to dry before injecting
- **Do not** inject through clothes
- **Do not** inject into skin that is sore, bruised, red, hard, scarred, or has stretch marks
- **Do not** inject into areas affected by psoriasis

STEP 3



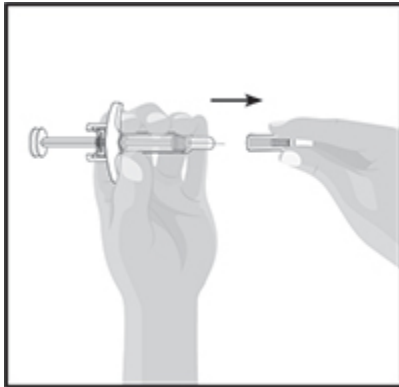
Check liquid

Hold the syringe with covered needle pointing down, as shown.

Check the liquid in the syringe.

- It is normal to see bubbles in the window
- The liquid should look clear to yellow and may contain tiny white or clear particles
- **Do not** use if liquid is cloudy or contains flakes or large particles

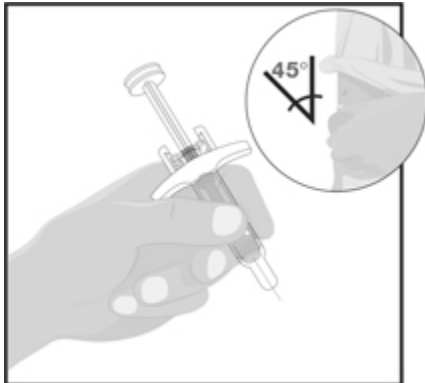
STEP 4



Removing the needle cover:

- Hold the syringe in one hand between the finger grip and needle cover
- With the other hand, gently pull the needle cover straight off
- **Do not** hold or pull plunger rod when removing the needle cover
- You may see a drop of liquid at the end of the needle. This is normal
- Throw away the needle cover
- **Do not** touch the needle with your fingers or let the needle touch anything

STEP 5

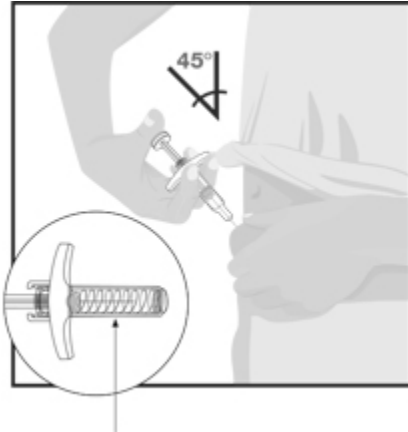


Hold the body of the syringe in one hand between the thumb and index finger, like you would a pencil.

Gently pinch the area of cleaned skin with your other hand and hold it firmly.

Insert the needle all the way into the skin at about a 45-degree angle using a quick, short movement. Keep the syringe steady at the same angle.

STEP 6



Needle guard

Slowly push the plunger rod all the way in until all of the liquid is injected.

Pull the needle out of the skin while keeping the syringe at the same angle.

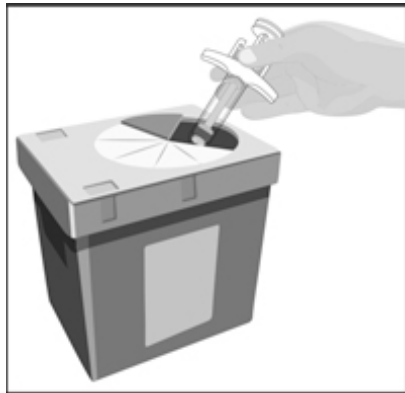
Slowly take your thumb off the plunger rod. The needle will then be covered by the needle guard.

- The needle guard will not activate unless all the liquid is injected
- Speak to your doctor, pharmacist or nurse if you think you have not given a full dose

Press a cotton ball or gauze pad where you have injected and hold for 10 seconds.

Do not rub the skin where you have injected. You may have slight bleeding from where you injected. This is normal.

STEP 7



Throw away the used syringe in a special disposal container right away after use.

- Do not throw away the used syringe in the household waste
- Your doctor, pharmacist or nurse will tell you how to return the full special disposal container

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