

PATIENT INFORMATION LEAFLET

SKYRIZI SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE 75MG/0.83mL (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 75 mg/0.83 mL prefilled syringe contains 75 mg of the active ingredient, risankizumab, in 0.83 mL of solution.

The other ingredients in the 75 mg/0.83 mL prefilled syringe are disodium succinate hexahydrate, succinic acid, sorbitol, polysorbate 20 and water for injection.

Information about certain ingredients in SKYRIZI

SKYRIZI 75 mg/0.83 mL contains less than 1 mmol sodium (23 mg) per 150 mg dose, i.e., essentially 'sodium-free'.

SKYRIZI 75 mg/0.83 mL contains 68 mg sorbitol per 150 mg dose.

4. DOSAGE FORM/APPEARANCE

SKYRIZI 75 mg/0.83 mL is a clear and colorless to slightly yellow liquid in a prefilled syringe with needle guard. Each carton contains 2 prefilled syringes.

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 75 mg/0.83 mL prefilled syringe 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 75 mg/0.83 mL prefilled syringe, each dose is given as two 75 mg injections.

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 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.

SKYRIZI 75 mg/0.83 mL liquid should look clear to slightly yellow. The liquid may contain tiny white or clear particles. Do not use if liquid is cloudy or contains flakes or large particles.

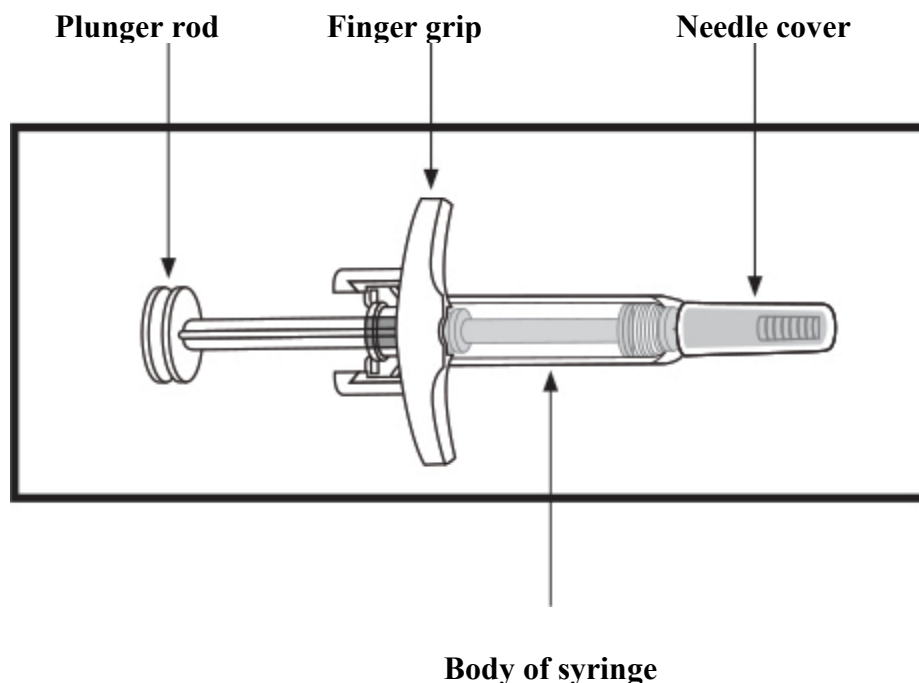
Ask your doctor, pharmacist or nurse how to throw away used syringes safely.

9. INSTRUCTIONS FOR USE

SKYRIZI 75 MG/0.83 ML PREFILLED SYRINGE

Please read complete instructions before using SKYRIZI

SKYRIZI prefilled syringe



Important information to know before you inject SKYRIZI

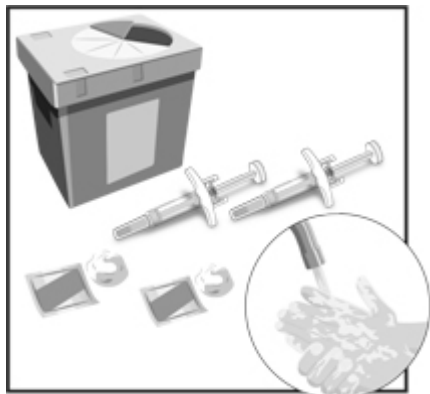
- Receive training on how to inject SKYRIZI before giving an injection. Talk to your doctor, pharmacist or nurse if you need help
- Mark the dates on your calendar so you know when to next use SKYRIZI
- Keep SKYRIZI in the original carton to protect from light until it is time to use it
- **Do not** inject if the liquid is cloudy or contains flakes or large particles. The liquid should look clear to slightly 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 syringe tray cover is broken or missing. 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 syringes 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



Place the following on a clean, flat surface:

- 2 prefilled syringes and 2 alcohol pads
- 2 cotton balls or gauze pads
- special disposal container

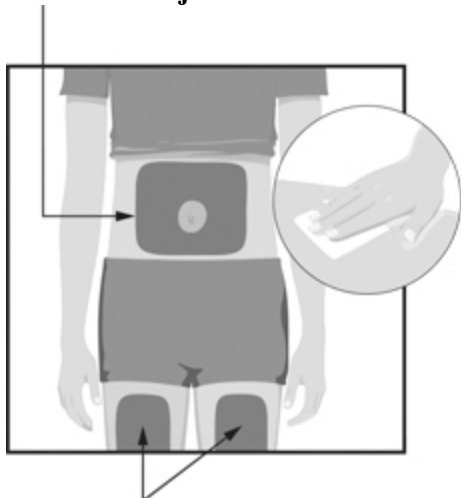
Wash and dry your hands.

Start with one syringe for first injection.

For a full dose, 2 injections are required, one after the other.

STEP 2

Areas to inject



Areas to inject

Choose from these 3 areas to inject:

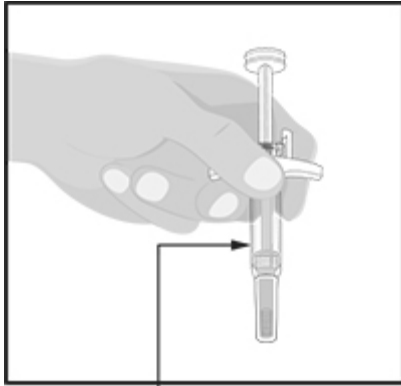
- front of left thigh
- front of right thigh
- belly (abdomen) at least 5 cm from the belly button (navel)

For the second syringe, inject at least 3 cm away from the first injection. **Do not** inject into the same place.

Before each 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



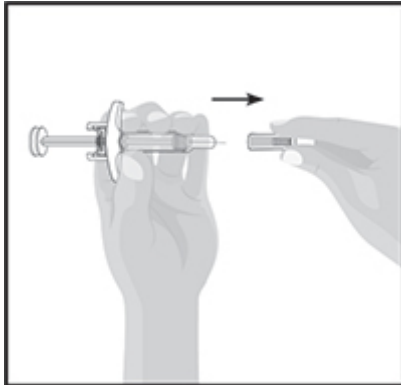
Check liquid

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 slightly yellow and may contain tiny white or clear particles
- **Do not** use if liquid is cloudy or contains flakes or large particles

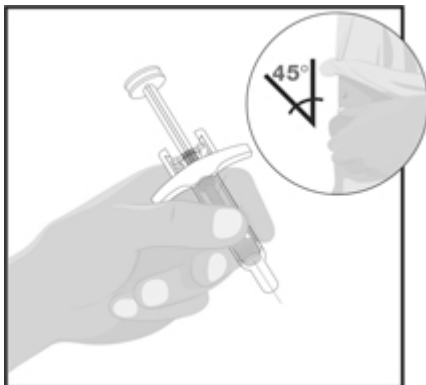
STEP 4



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



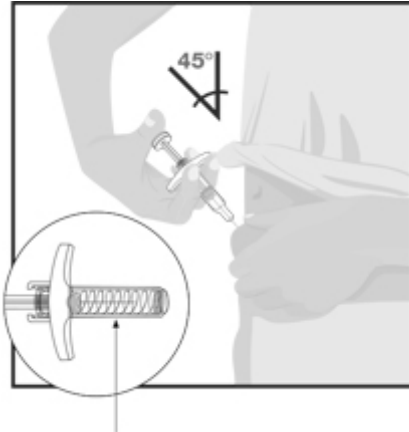
Hold the body of the syringe in one hand between the thumb and index finger, like you would a pencil.

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.

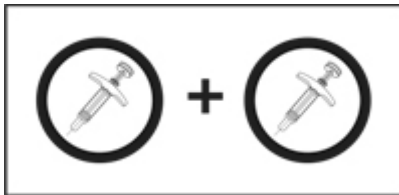
Slowly take your thumb off the plunger rod. The needle will then be covered by the needle guard.

- 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

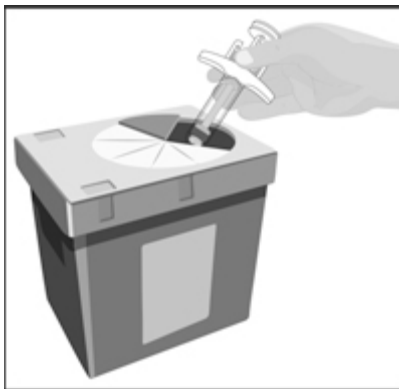


2 Injections Required

For a full dose, two injections are needed, one after the other.

- Repeat Steps 2 through 6 with the second syringe
- Inject the second syringe straight after the first injection but at least 3 cm away from the first injection

STEP 8



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

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

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CCDS05180622
Date of issue: DD MMM YYYY