

Package leaflet: Information for the patient

Skyrizi 55 mg solution for injection in pre-filled syringe risankizumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This leaflet has been written for the person taking the medicine. If you are the parent or caregiver who will give Skyrizi to a child or adolescent, please read this information carefully.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Skyrizi is and what it is used for
2. What you need to know before you use Skyrizi
3. How to use Skyrizi
4. Possible side effects
5. How to store Skyrizi
6. Contents of the pack and other information
7. Instructions for use

1. What Skyrizi is and what it is used for

Skyrizi contains the active substance risankizumab.

Skyrizi is used to treat plaque psoriasis in children and adolescents from 6 to less than 18 years of age.

How Skyrizi works

This medicine works by stopping a protein in the body called 'IL-23', which causes inflammation. Skyrizi reduces inflammation and can therefore help reduce symptoms of plaque psoriasis such as burning, itching, pain, redness, and scaling.

2. What you need to know before you use Skyrizi

Do not use Skyrizi

- if you are allergic to risankizumab or any of the other ingredients of this medicine (listed in section 6).
- if you have an infection, including active tuberculosis, which your doctor thinks is important.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before and during the use of Skyrizi:

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

It is important to keep a record of the batch number of your Skyrizi. Every time you get a new pack of Skyrizi, note down the date and the batch number (which is on the packaging after “Lot”) and keep this information in a safe place.

Serious allergic reactions

Skyrizi can cause serious side effects, including serious allergic reactions (‘anaphylaxis’).

Tell your doctor or seek medical help immediately if you notice any signs of an allergic reaction while you are taking Skyrizi such as:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- low blood pressure, which can cause dizziness or light-headedness
- severe itching of the skin, with a red rash or raised bumps

Children and adolescents

Skyrizi is not recommended for children under 6 years of age.

Other medicines and Skyrizi

Tell your doctor, pharmacist or nurse:

- if you are using, have recently used or might use any other medicines.
- if you have recently had or are going to have a vaccination. You should not be given certain types of vaccines while using Skyrizi.

If you are not sure, talk to your doctor, pharmacist or nurse before and during the use of Skyrizi.

Pregnancy, contraception and breast-feeding

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 can become pregnant, you should use contraception while using this medicine and for at least 21 weeks after your last dose of Skyrizi.

If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine.

Driving and using machines

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

Skyrizi contains polysorbate and sodium

This medicine contains 0.07 mg of polysorbate 20 in each 55 mg dose. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

This medicine contains less than 1 mmol sodium (23 mg) per pre-filled syringe, that is to say essentially ‘sodium-free’.

3. How to use Skyrizi

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

This medicine is given as an injection under your skin (called a ‘subcutaneous injection’).

How much Skyrizi to use

Age and body weight	How much and how often to take?
Children and adolescents 6 to less than 18 years of age weighing less than 40 kg	Each dose is 55 mg given as a single injection. After the first dose, you will have the next dose 4 weeks later, and then every 12 weeks.
Children and adolescents 6 to less than 18 years of age weighing at least 40 kg	Each dose is 150 mg given as a single 150 mg injection. A 150 mg pre-filled pen or 150 mg pre-filled syringe is available. After the first dose, you will have the next dose 4 weeks later, and then every 12 weeks.

You and your doctor, pharmacist or nurse will decide if you should inject this medicine 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 injection after they have been trained.

Read section 7 ‘Instructions for use’ at the end of this leaflet before injecting Skyrizi.

If you use more Skyrizi than you should

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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. Possible side effects

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

Serious side effects

Allergic reactions – these may need urgent treatment. Tell your doctor or get emergency medical help straight away if you notice any of the following signs:

Serious allergic reactions (‘anaphylaxis’) are rare in people taking Skyrizi (may affect up to 1 in a 1 000 people). Signs include:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- low blood pressure, which can cause dizziness or light-headedness

Talk to your doctor or get medical help immediately if you have the following symptoms.

Symptoms of a 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 (such as redness or pain)
- itching
- headache
- rash
- eczema

Uncommon: may affect up to 1 in 100 people

- small raised red bumps on the skin
- hives (urticaria)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Skyrizi

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

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

Store in a refrigerator (2°C - 8°C). Do not freeze.

Keep the pre-filled syringe in the outer carton in order to protect from light.

If needed, you may also store the pre-filled syringe out of the refrigerator (up to a maximum of 25°C) for up to 24 hours in the original carton to protect from light.

Do not use this medicine if the liquid is cloudy or contains flakes or large particles.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Skyrizi contains

- The active substance is risankizumab. Each pre-filled syringe contains 55 mg of risankizumab in 0.37 mL solution.
- The other ingredients are sodium acetate trihydrate, acetic acid, trehalose dihydrate, polysorbate 20 and water for injections. See section 2 “Skyrizi contains polysorbate and sodium”.

What Skyrizi looks like and contents of the pack

Skyrizi is a clear and colourless to yellow liquid in a pre-filled syringe with needle guard. The liquid may contain tiny white or clear particles.

Each pack contains 1 pre-filled syringe.

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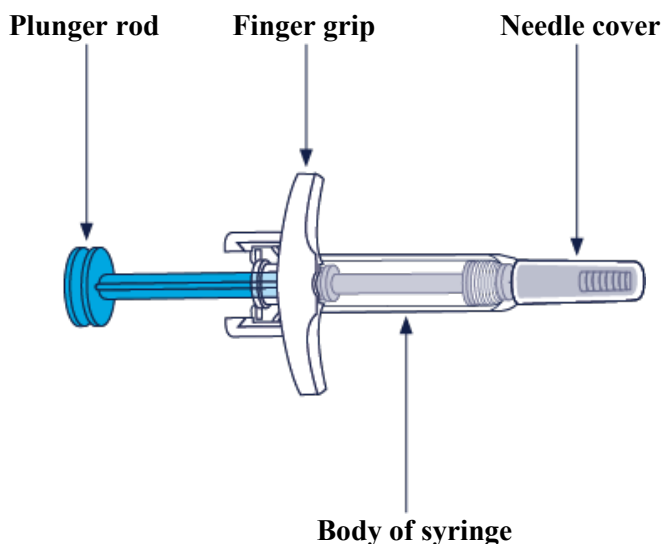
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To listen to or request a copy of this leaflet in Braille, large print or audio, please contact the Marketing Authorisation Holder.

7. Instructions for use

Please read all of section 7 before using Skyrizi

Skyrizi pre-filled syringe



Important information to know before you inject Skyrizi

- You should receive training on how to inject Skyrizi before giving an injection. Talk to your doctor, pharmacist or nurse if you need help
- In children and adolescents 10 to less than 18 years of age, it is recommended that Skyrizi is given by or under supervision of an adult
- In children 6 to less than 10 years of age, Skyrizi should be given by an adult
- Mark the dates on your calendar so you know when to inject Skyrizi
- Keep Skyrizi in the original carton to protect the medicine 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** shake the syringe
- Wait to remove the needle cover until just before the injection

Return this medicine to the pharmacy

- if the expiry date (EXP) has passed
- if the liquid has ever been frozen (even if thawed)
- if the syringe has been dropped
- if the syringe has been damaged (for example, the needle is bent or the plunger rod is not connected to the body of the syringe)
- if the carton perforations are broken

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.

- Skyrizi should not be warmed in any other way (for example, in a microwave or in hot water)
- Keep the syringe in the carton until ready to inject

Follow the steps below each time you use Skyrizi

STEP 1



Remove the pre-filled syringe from the cardboard sleeve by holding the finger grip.

- **Do not** hold or pull plunger rod when removing the pre-filled syringe from the sleeve
- **Do not** remove the needle cover until you are ready to inject

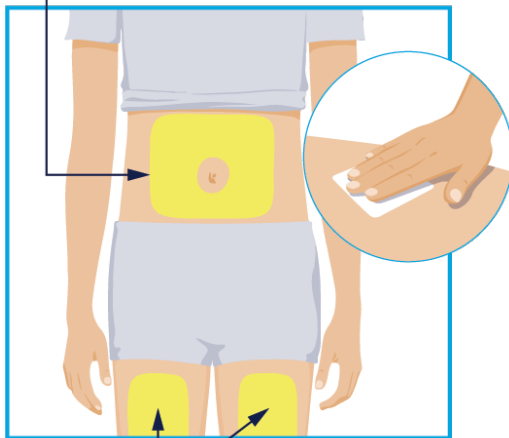
Place the following items on a clean, flat surface:

- 1 pre-filled syringe
- 1 alcohol pad (not included in the carton)
- 1 cotton ball or gauze pad (not included in the carton)
- special disposal container (not included in the carton)

Wash and dry your hands.

STEP 2

Areas to inject



Areas to inject

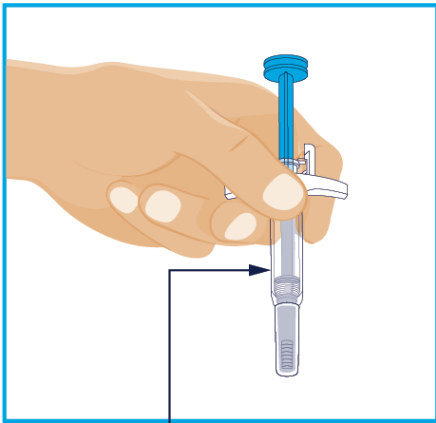
Choose from these 3 areas to inject:

- front of left thigh
- front of right thigh
- your belly (abdomen) at least 5 cm from your 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



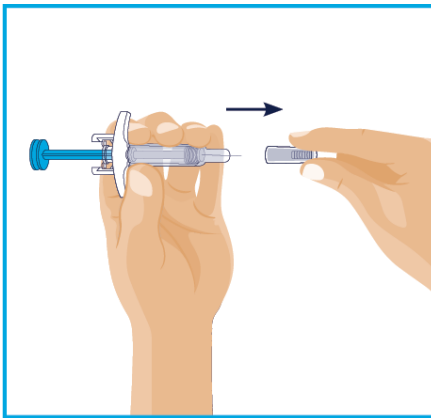
Check liquid

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

Check the liquid in the syringe.

- It is normal to see bubbles in the window, they do not need to be removed
- 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

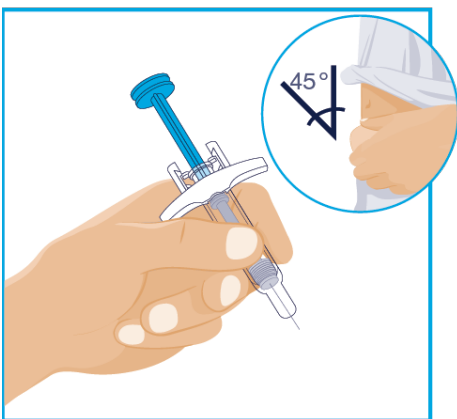
STEP 4



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 the 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
- **Do not** use if the syringe has been dropped
- **Do not** use if the syringe has been damaged (for example, the needle is bent or the plunger rod is not connected to the body of the syringe)

STEP 5

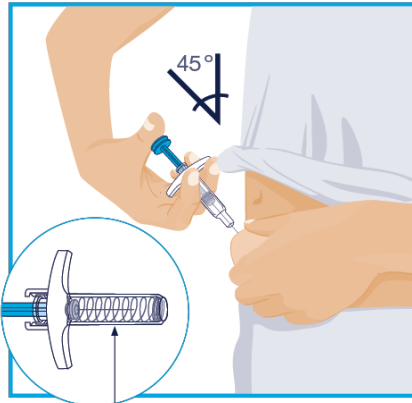


Hold the body of the syringe in one hand between the thumb and index finger, like you would a pencil.

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 straight 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