

Package leaflet: Information for the patient

Skyrizi 75 mg solution for injection in pre-filled syringe risankizumab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

- 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 adults with moderate to severe plaque psoriasis.

How Skyrizi works

This medicine works by stopping a protein in the body called 'IL-23', which causes inflammation. It reduces the inflammation. It also reduces symptoms of 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.

Allergic reactions

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
- severe itching of the skin, with a red rash or raised bumps

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.

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 are a woman who 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 sorbitol and sodium

This medicine contains 68 mg sorbitol per 150 mg dose.

This medicine contains less than 1 mmol sodium (23 mg) per 150 mg dose, 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 2 injections under your skin (called 'subcutaneous injections').

How much Skyrizi to use

The dose is 150 mg given as two 75 mg injections.

	How much?	When?
1st dose	150 mg (two 75 mg injections)	When your doctor tells you
2nd dose	150 mg (two 75 mg injections)	4 weeks after 1 st dose
Further doses	150 mg (two 75 mg injections)	Every 12 weeks starting after 2 nd dose

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 injections after they have been trained.

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

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

Talk to your doctor or get medical help immediately if you have 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

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. You can also report side effects directly via the national reporting system listed in [Appendix V](#). 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 syringes in the original carton in order 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 75 mg of risankizumab in 0.83 ml solution.
- The other ingredients are disodium succinate hexahydrate, succinic acid, sorbitol, polysorbate 20 and water for injections.

What Skyrizi looks like and contents of the pack

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

Each pack contains 2 pre-filled syringes and 2 alcohol pads.

Marketing Authorisation Holder

AbbVie Deutschland GmbH & Co. KG
Knollstrasse
67061 Ludwigshafen
Germany

Manufacturer

AbbVie S.r.l.
04011 Campoverde di Aprilia
(Latina)
Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

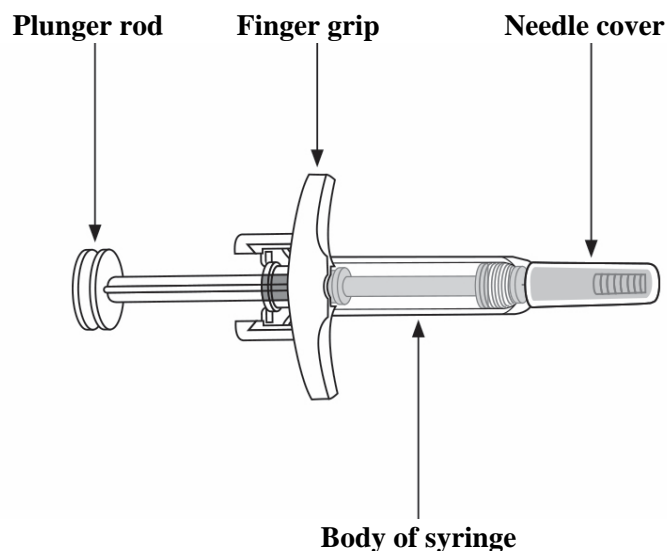
Detailed and updated information on this product is available by scanning the QR code included below or on the outer carton with a smartphone. The same information is also available at the following URL:
www.skyrizi.eu

QR code to be included

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

7. Instructions for use

Please read all of section 7 before using Skyrizi



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
- 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 slightly 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 or damaged
- if the syringe paper tray cover is broken or missing

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 syringes in the carton until ready to inject

Follow the steps below each time you use Skyrizi

STEP 1



Place the following items on a clean, flat surface:

- 2 pre-filled syringes and 2 alcohol pads (included in the carton)
- 2 cotton balls or gauze pads (not included in the carton)
- Special disposal container (not included in the carton)

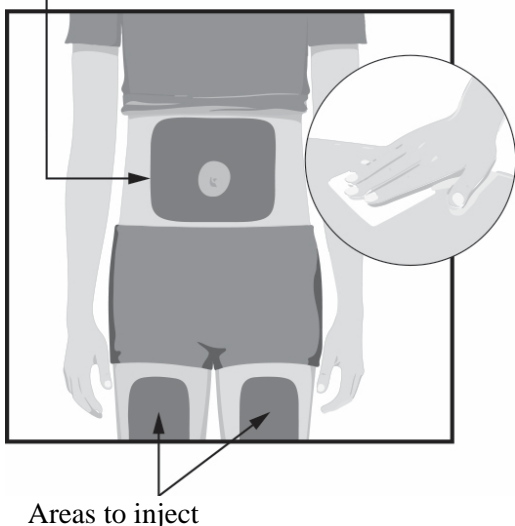
Wash and dry your hands.

Start with one syringe for the 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:

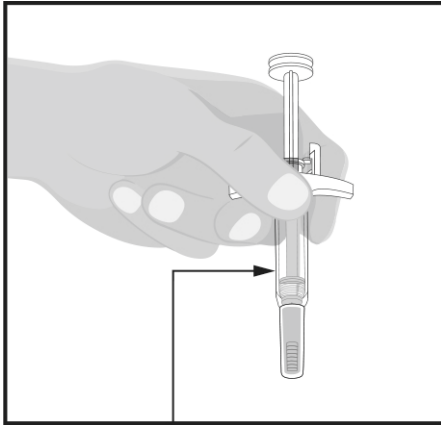
- front of left thigh
- front of right thigh
- your belly (abdomen) at least 5 cm from your belly button (navel)

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



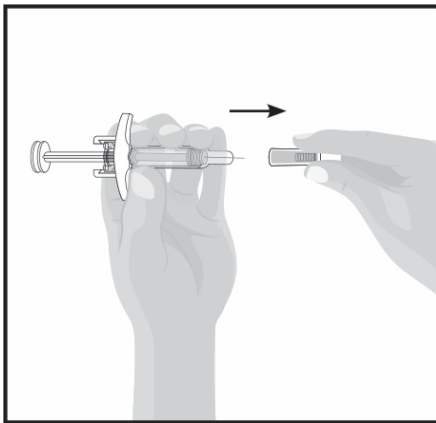
Check liquid

Hold the syringe with the 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 the liquid is cloudy or contains flakes or large particles

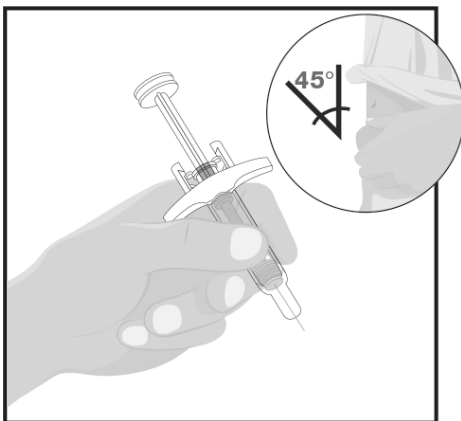
STEP 4



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

STEP 5

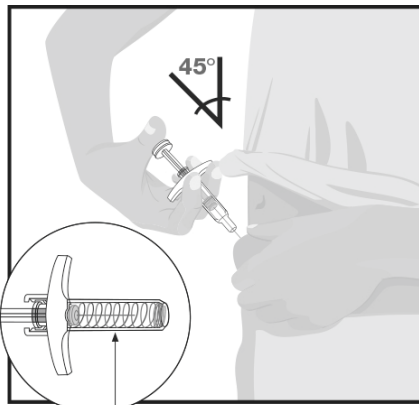


Hold the body of the syringe in one hand between the thumb and index finger, like you would a pencil.

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.

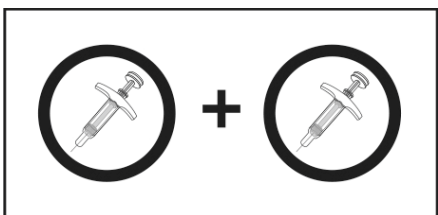
Slowly take your thumb off the plunger rod. The needle will then be covered by the needle guard.

- 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

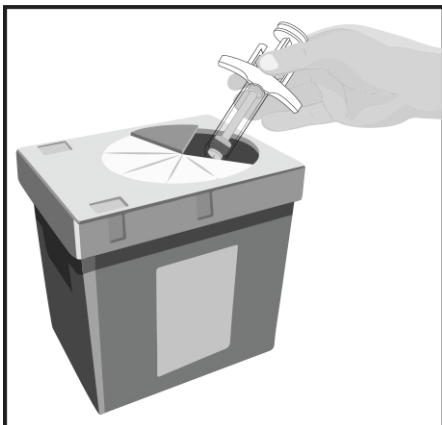


2 Injections Required

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 straight 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