

**Skyrizi® 75 mg solution for injection in pre-filled syringe**

(risankizumab)

UK620635P97-A2.0

**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.

This product is called Skyrizi 75 mg solution for injection in pre-filled syringe but will be referred to as Skyrizi throughout the leaflet.

**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 the following inflammatory diseases:

- Plaque psoriasis
- Psoriatic arthritis

**How Skyrizi works**

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

**Plaque psoriasis**

Skyrizi is used to treat adults with moderate to severe plaque psoriasis. Skyrizi reduces inflammation and can therefore help reduce symptoms of plaque psoriasis such as burning, itching, pain, redness, and scaling.

**Psoriatic arthritis**

Skyrizi is used to treat adults with psoriatic arthritis. Psoriatic arthritis is a disease that causes inflamed joints and psoriasis. If you have active psoriatic arthritis, you may first be given other medicines. If these medicines do not work well enough, you will be given Skyrizi either alone or in combination with other medicines to treat your psoriatic arthritis.

Skyrizi reduces 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 slow down 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.

**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 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, polysorbate and sodium**

This medicine contains 68 mg sorbitol per 150 mg dose.

This medicine contains 0.34 mg of polysorbate 20 in each 150 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 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?
<b>1<sup>st</sup> dose</b>	150 mg (two 75 mg injections)	When your doctor tells you
<b>2<sup>nd</sup> dose</b>	150 mg (two 75 mg injections)	4 weeks after 1 <sup>st</sup> dose
<b>Further doses</b>	150 mg (two 75 mg injections)	Every 12 weeks starting after 2 <sup>nd</sup> 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**

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, 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

**United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

**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.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

**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. See section 2, "Skyrizi contains sorbitol, polysorbate and sodium".

**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.

**Manufacturer:**

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

**Procured from within the EU and repackaged for the PL Holder:**

Abacus Medicine Ltd., Abbey House, 282 Farnborough Road, Farnborough, GU14 7NA, United Kingdom

Skyrizi 75 mg solution for injection in pre-filled syringe  
PL 45763/0635

**POM**

Skyrizi® is a registered trademark of AbbVie Biotechnology Ltd

For any information about this medicine, please contact the local representative of the Product Licence Holder:

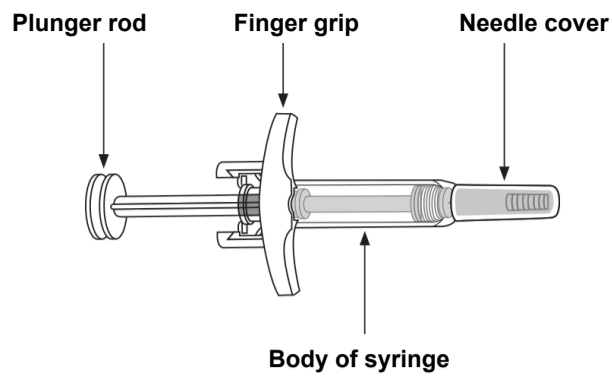
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**This leaflet was last revised on 10.10.2025.**

**Blind or partially sighted?  
Is this leaflet hard to  
see or read?  
Call 02036301310 or write to  
[info@abacusmedicine.com](mailto:info@abacusmedicine.com)  
to obtain the leaflet in a  
format suitable for you.**

## 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)

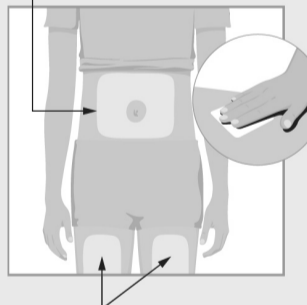
Wash and dry your hands.

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:

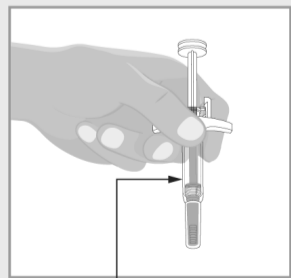
- front of left thigh
- front of right thigh
- your belly (abdomen) at least 5 cm from your belly button (navel)

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



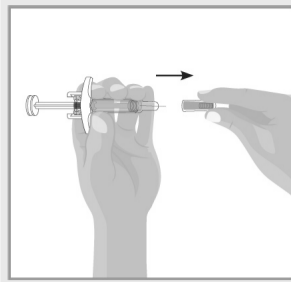
##### Check liquid

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

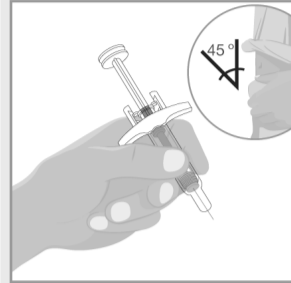
#### STEP 4



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

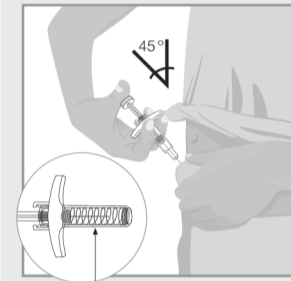


Hold the body of the syringe in one hand between the thumb and index finger, like you would a pencil.

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.

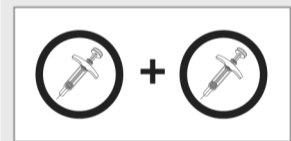
The needle will then be covered by the needle guard.

- 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