

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

# Skyrizi™ 75 mg Solution for injection in a Pre-filled Syringe

## The active ingredient and its concentration:

Risankizumab 90 mg/1 ml  
Each pre-filled syringe contains 75 mg of risankizumab in 0.83 ml solution.

For the list of inactive and allergenic ingredients - please see section 6 "Further Information" in this leaflet.

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

## 1. WHAT IS THE MEDICINE INTENDED FOR?

Skyrizi is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

## Therapeutic group:

Immunosuppressive agents, interleukin inhibitors.

Skyrizi 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. BEFORE USING THE MEDICINE

<p><b>Do not use the medicine if:</b></p> <ul style="list-style-type: none"><li>• you are sensitive (allergic) to risankizumab or to any of the additional ingredients contained in the medicine (listed in section 6).</li><li>• you have an infection, including active tuberculosis, which your doctor thinks is important.</li></ul>
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## Special Warning Regarding Using The Medicine

### Before treatment and during the use of Skyrizi, inform the doctor 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 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.

## Drug-Drug Interactions

**If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.** Especially 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, breastfeeding and fertility

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.

There is no adequate information regarding the use of Skyrizi in pregnancy; therefore, as a precautionary measure, it is recommended to avoid the use of the medicine during pregnancy.

It is not known whether Skyrizi is excreted into human milk. 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.

## Important information about some of the medicines ingredients

Please see section 6 "Further Information" in this leaflet.

## 3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

The usual dosage is generally 150 mg given as two 75 mg injections under your skin ('subcutaneous injection').

	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, nurse or pharmacist 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.

## Do not exceed the recommended dose.

Detailed instructions on how to inject Skyrizi are provided in section 7 'Instructions for use'.

## If you accidentally have taken a higher dosage

If you accidentally inject Skyrizi more than you should or the dose has been given sooner than prescribed or if a child accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the outer carton with you.

## If you forget to inject Skyrizi

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

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your condition, do not stop treatment with the medicine without consulting the doctor.

## 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.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.**

## 4. SIDE EFFECTS

As with any medicine, use of Skyrizi may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of 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 if you get any of the following side effects

### Very common side effects (effects that occur in more than 1 in 10 users):

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

### Common side effects (effects that occur in 1-10 out of 100 users):

- feeling tired
- fungal skin infection
- injection site reactions (such as redness or pain)
- itching
- headache

### Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- small raised red bumps on the skin

**If a side effect has occurred, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.**

### Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects due to Drug Treatment" found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

## 5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, must be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the syringe label and outer carton. The expiry date refers to the last day of that month.
- 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.
- Storage Conditions: Store in a refrigerator (2°C – 8°C). Do not freeze.

## 6. FURTHER INFORMATION

### What Skyrizi contains

In addition to the active ingredient, the medicine also contains:

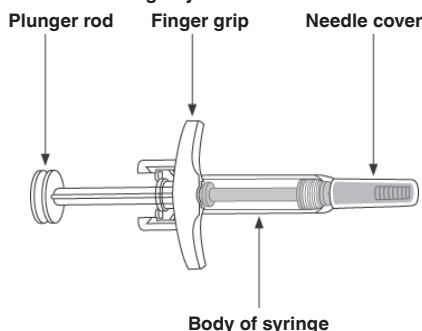
- Sorbitol, disodium succinate hexahydrate, polysorbate 20, succinic acid and water for injections
- This medicine contains 68 mg sorbitol per 150 mg dose. This medicine contains less than 1 mmol sodium (23 mg) per 150 mg dose, that is to say essentially 'sodium-free'.
- **What the medicine looks like 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.
- **License holder and its address:** AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel.
- **Manufacturer name and address:** AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061, Ludwigshafen, Germany.

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by the Ministry of Health in January 2020 and was updated in accordance with the Ministry of Health guidelines in March 2020.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 163-46-36028

## 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

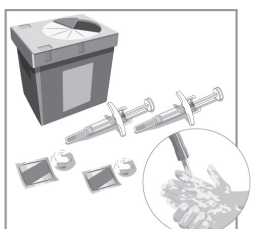
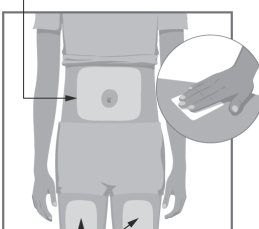
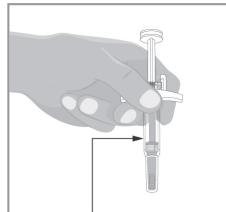
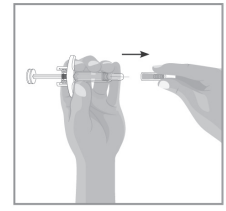
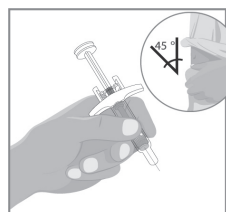
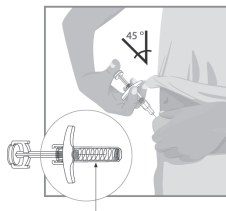

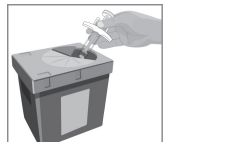
### Return this medicine to the pharmacy

- 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

<b>STEP 1</b> 	Place the following items on a clean, flat surface: <ul style="list-style-type: none"><li>• 2 pre-filled syringes and 2 alcohol pads (included in the carton)</li><li>• 2 cotton balls or gauze pads (not included in the carton)</li><li>• Special disposal container (not included in the carton)</li></ul> Wash and dry your hands. Start with one syringe for the first injection.
<b>STEP 2</b> Areas to inject 	Choose from these 3 areas to inject: <ul style="list-style-type: none"><li>• front of left thigh</li><li>• front of right thigh</li><li>• your belly (abdomen) at least 5 cm from your belly button (navel)</li></ul> For the second syringe, inject at least 3 cm away from the first injection. <b>Do not</b> inject into the same place.
<b>STEP 3</b> Check liquid 	Hold the syringe with the covered needle pointing down, as shown. Check the liquid in the syringe. <ul style="list-style-type: none"><li>• It is normal to see bubbles in the window</li><li>• The liquid should look clear to slightly yellow and may contain tiny white or clear particles</li><li>• <b>Do not</b> use if the liquid is cloudy or contains flakes or large particles</li></ul>
<b>STEP 4</b> 	Removing the needle cover: <ul style="list-style-type: none"><li>• Hold the syringe in one hand between the finger grip and needle cover</li><li>• With the other hand, gently pull the needle cover straight off</li><li>• <b>Do not</b> hold or pull the plunger rod when removing the needle cover</li><li>• You may see a drop of liquid at the end of the needle. This is normal</li><li>• Throw away the needle cover</li><li>• <b>Do not</b> touch the needle with your fingers or let the needle touch anything</li></ul>
<b>STEP 5</b> 	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.
<b>STEP 6</b> 	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. <ul style="list-style-type: none"><li>• The needle guard will not activate unless all the liquid is injected</li><li>• Speak to your doctor, pharmacist or nurse if you think you have not given a full dose</li></ul> Press a cotton ball or gauze pad where you have injected and hold for 10 seconds. <b>Do not</b> rub the skin where you have injected. You may have slight bleeding from where you injected. This is normal
<b>STEP 7</b> 	<b>For a full dose, two injections are needed, one after the other.</b> <ul style="list-style-type: none"><li>• Repeat Steps 2 through 6 with the second syringe</li><li>• Inject the second syringe straight after the first injection but at least 3 cm away from the first injection</li></ul>
<b>STEP 8</b> 	Throw away used syringes in a special disposal container straight after use. <ul style="list-style-type: none"><li>• <b>Do not</b> throw away used syringes in the household waste</li><li>• Your doctor, pharmacist or nurse will tell you how to return the full special disposal container</li></ul>