

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

The medicine is dispensed with a doctor's prescription only

Skyrizi® 150 mg

Solution for Injection in a Pre-filled Pen

Active ingredient and its concentration: Each pre-filled pen contains 150 mg of risankizumab in 1 mL solution

For the list of inactive and allergenic ingredients – please see section 6 “Further Information” in this leaflet.

Read the 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?

Plaque psoriasis

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

Psoriatic arthritis

Skyrizi, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).

Therapeutic group:

Immunosuppressive agents, interleukin inhibitors.

Skyrizi works by blocking a protein in the body called ‘IL-23’, which causes inflammation.

Plaque psoriasis

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

Psoriatic arthritis

Skyrizi is indicated for the treatment of 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. BEFORE USING THE MEDICINE

Do not use the medicine if:

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

Special Warnings Regarding Use of 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 using 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 intended 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 of childbearing age, 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 breastfeeding or are planning to breastfeed, 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 ingredients of the medicine

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

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

Each dose is 150 mg given as a single injection. 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.

Do not exceed the recommended dose.

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

If you accidentally have injected a higher dosage

If you accidentally inject more Skyrizi 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 health 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 continue 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 one in 10 users):

- Upper respiratory tract 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
- Rash

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

- Small raised red bumps on the skin
- Urticaria

If a side effect occurs, 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 of Drug Treatment” found on the Ministry of Health homepage (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 reach and sight 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) that appears on the pen label and outer carton. The expiry date refers to the last day of that month.
- Storage conditions: Store in a refrigerator (2°C–8°C). Do not freeze.
- Keep the pre-filled pen in the original carton in order to protect from light.
- If needed, you may also store the pre-filled pen 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. FURTHER INFORMATION

What Skyrizi contains

In addition to the active ingredient, the medicine also contains: Trehalose dihydrate, sodium acetate trihydrate, polysorbate 20, acetic acid glacial and water for injection

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

What the medicine looks like and contents of the pack? Skyrizi is a clear and colourless to yellow liquid in a pre-filled pen. The liquid may contain tiny white or clear particles. Each pack contains 1 pre-filled pen.

License holder and its address: AbbVie Biopharmaceuticals Ltd., 4 Haharash, Hod Hasharon, Israel.

Manufacturer name and its address: AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061, Ludwigshafen, Germany.

Revised in April 2023 according to MoH’s guidelines

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 169-73-36871

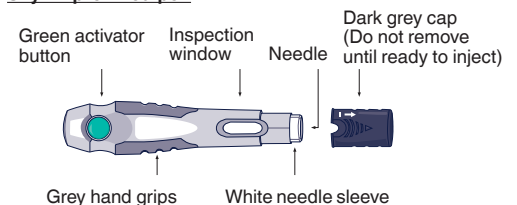
For additional information and the support program call center call *6718



7. INSTRUCTIONS FOR USE

Please read all of section 7 before using Skyrizi

Skyrizi pre-filled pen



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
- Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for **30 to 90 minutes** before injecting
- Do not** inject if the liquid in the inspection window 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 pen
- Wait to remove the dark grey cap 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 pen has been dropped or damaged
- If the carton perforations are broken

Follow the steps below each time you use Skyrizi

<p>STEP 1</p>	<p>Take the carton out of the refrigerator and leave it at room temperature, out of direct sunlight, for 30 to 90 minutes before injecting.</p> <ul style="list-style-type: none"> Do not remove the pen from the carton while allowing Skyrizi to reach room temperature Do not warm Skyrizi in any other way. For example, do not warm it in a microwave or in hot water Do not use the pen if liquid has been frozen, even if it has been thawed
<p>STEP 2</p>	<p>Place the following items on a clean, flat surface:</p> <ul style="list-style-type: none"> 1 pre-filled pen 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) <p>Wash and dry your hands.</p>

<p>STEP 3</p>	<p>Choose from these 3 areas to inject:</p> <ul style="list-style-type: none"> front of left thigh front of right thigh your belly (abdomen) at least 5 cm from your belly button (navel) <p>Before the injection, wipe where you will inject in a circular motion with an alcohol pad.</p> <ul style="list-style-type: none"> 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
<p>STEP 4</p>	<p>Hold the pen with the dark grey cap pointing up, as shown.</p> <ul style="list-style-type: none"> Pull the dark grey cap straight off Throw the dark grey cap away <p>Check the liquid through the inspection window.</p> <ul style="list-style-type: none"> It is normal to see bubbles in the liquid 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
<p>STEP 5</p> <p>Abdomen or Thigh</p>	<p>Hold the pen with your fingers on the grey hand grips.</p> <p>Turn the pen so that the white needle sleeve points toward the injection site and you can see the green activator button.</p> <p>Gently squeeze the skin at your injection site to make a raised area and hold it firmly.</p> <p>Place the white needle sleeve straight (90° angle) against the raised injection site.</p>

<p>STEP 6</p> <p>First “click” 15 seconds</p>	<p>Hold the pen so that you can see the green activator button and inspection window.</p> <p>Push and keep pressing the pen down against the raised injection site.</p> <ul style="list-style-type: none"> The pen will activate only if the white needle sleeve is pressed down against the injection site before pressing the green activator button <p>Press the green activator button and hold the pen for 15 seconds.</p> <ul style="list-style-type: none"> A loud “click” means the start of the injection
<p>STEP 7</p> <p>Second “click”</p>	<p>Keep pressing the pen down against the injection site.</p> <p>The injection is complete when:</p> <ul style="list-style-type: none"> the pen has made a second “click” or the yellow indicator has filled the inspection window. <p>This takes up to 15 seconds.</p>
<p>STEP 8</p>	<p>When the injection is complete, slowly pull the pen out from the skin.</p> <p>The white needle sleeve will cover the needle tip and make another “click.”</p> <p>After completing the injection, place a cotton ball or gauze pad on the skin at the injection site.</p> <ul style="list-style-type: none"> Do not rub the injection site Slight bleeding at the injection site is normal
<p>STEP 9</p>	<p>Throw away the used pen in a special disposal container straight after use.</p> <ul style="list-style-type: none"> Do not throw away the used pen in the household waste Your doctor, pharmacist or nurse will tell you how to return the full special disposal container