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

This medicine is dispensed with a doctor's prescription only

Skyrizi® 600 mg

Concentrated solution for solution for infusion

The active ingredient and its concentration:

Each vial contains:

600 mg of risankizumab in 10 ml solution (60 mg/1 ml).

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?

Skyrizi is indicated for the treatment of patients 16 years and older with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy, or if such therapies are not advisable.

Skyrizi is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy.

Therapeutic group:

Immunosuppressive agents, interleukin inhibitors.

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

Crohn's disease is an inflammatory disease of the digestive tract. If you have active Crohn's disease you will first be given other medicines. If these medicines do not work well enough, you will be given Skyrizi to treat your Crohn's disease.

Ulcerative colitis is an inflammatory disease of the large bowel. If you have active ulcerative colitis you will first be given other medicines. If these medicines do not work well enough or if you cannot take them, you will be given Skyrizi to treat your ulcerative colitis. Skyrizi reduces the inflammation and can therefore help to reduce the signs and symptoms of your disease.

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.

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 using 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

For treatment of Crohn's disease:

Skyrizi is not intended for children and adolescents under 16 years of age. There are no data regarding the efficacy and safety of Skyrizi in children and adolescents under 16 years of age.

For treatment of ulcerative colitis:

Skyrizi is not intended for children and adolescents under 18 years of age. There are no data regarding the efficacy and safety of Skyrizi in children and adolescents under 18 years of age.

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 or has a negligible effect on your driving and use of machines.

Skyrizi contains polysorbate and sodium

This medicine contains 2 mg of polysorbate 20 in each 600 mg dose and 4 mg of polysorbate 20 in each 1,200 mg dose. Polysorbate may cause an allergic reaction. Tell your doctor if you have any known allergies.

This medicine contains less than 1 mmol sodium (23 mg) per 600 mg and 1,200 mg dose, that is to say essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

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

Check with your 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. Generally, the usual dosage is:

You will begin treatment with Skyrizi with a starting dose which will be given by your doctor or nurse through a drip in your arm (intravenous infusion).

Starting doses

	How much?	When?
Crohn's disease	600 mg	When your doctor tells you
	600 mg	4 weeks after 1st dose
	600 mg	4 weeks after 2nd dose

	How much?	When?
Ulcerative colitis	1,200 mg	When your doctor tells you
	1,200 mg	4 weeks after 1st dose
	1,200 mg	4 weeks after 2nd dose

Afterwards, you will receive Skyrizi as an injection under your skin. See patient leaflet for Skyrizi 180 mg and 360 mg solution for injection in a cartridge.

Maintenance doses

	How much?		When?
Crohn's disease	**1st maintenance dose**	360 mg	4 weeks after the last starting dose (at Week 12)
	Further doses	360 mg	Every 8 weeks, after the 1st maintenance dose

	How much?		When?
Ulcerative colitis	**1st maintenance dose**	180 mg or 360 mg	4 weeks after the last starting dose (at Week 12)
	Further doses	180 mg or 360 mg	Every 8 weeks, after the 1st maintenance dose

If you forget to inject Skyrizi

If you forget or miss the appointment for any of your doses, contact your doctor to rescedule your appointment as soon as you remember.

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

Allergic reactions – these may need urgent treatment. Refer to 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 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 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 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
- Rash
- Eczema

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

- Small raised red bumps on the skin
- Hives (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 due to 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 vial 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 vial in the original carton in order to protect from light.
- Do not shake the Skyrizi vial. Prolonged vigorous shaking can damage the medicine.
- Do not use this medicine if the liquid is cloudy or contains flakes or large particles.
- Each vial is for single use only.
- Do not throw away any medicines via wastewater or household waste. 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.

  Please see section 2 "Skyrizi contains polysorbate and sodium".

- **What the medicine looks like and contents of the pack**

  Skyrizi is a clear and colourless to slightly yellow liquid in a vial. The liquid may contain tiny white or clear particles.

  Each pack contains 1 vial.

- **License holder and its address:** AbbVie Biopharmaceuticals Ltd., 4 Haharash, Hod Hasharon, Israel.
- **Manufacturer name and its address:** AbbVie Inc., 1N Waukegan Road, North Chicago, IL 60064, USA
- Revised in August 2025.
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health: 172-10-37478**

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

SKY 600 APL AUG25_CL_P4

המידע הבא מיועד לאנשי צוות רפואי בלבד

المعلومات التالية مخصصة لأفراد الطاقم الطبي فقط

The following information is intended for healthcare professionals only

Traceability

In order to improve the traceability of biological medicinal products, the tradename and the batch number of the administered product should be clearly recorded.

Instructions for use

1. This medicinal product should be prepared by a healthcare professional using aseptic technique.
2. It must be diluted before administration.
3. The solution for infusion is prepared by dilution of the concentrate into an infusion bag or glass bottle containing 5% dextrose in water (D5W) or sodium chloride 9 mg/ml (0.9%) solution for infusion to a final concentration of approximately 1.2 mg/ml to 6 mg/ml. Refer to table below for dilution instructions based on patient's indication.

Indication	Intravenous induction dose	Number of 600 mg/10 ml vials	Total volume of 5% dextrose or sodium chloride 9 mg/ml (0.9%) solution for infusion
Crohn's disease	600 mg	1	100 ml, or 250 ml, or 500 ml
Ulcerative colitis	1,200 mg	2	250 ml, or 500 ml

4. The solution in the vial and dilutions should not be shaken.
5. Prior to the start of the intravenous infusion, the content of the infusion bag or glass bottle should be at room temperature.
6. Infuse the diluted solution over a period of at least one hour for the 600 mg dose; at least two hours for the 1,200 mg dose.
7. The vial solution should not be administered concomitantly in the same intravenous line with other medicinal products.

Each vial is for single use only and any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Storage of diluted solution:

Chemical and physical in-use stability has been demonstrated for 20 hours at 2°C to 8°C (protected from light) or up to 4 hours (cumulative time from start of dilution to start of infusion) at room temperature (protected from sunlight). Exposure to indoor light is acceptable during room temperature storage and administration.
From a microbiological point of view, the prepared infusion should be used immediately. If not used immediately, in-use storage time and conditions prior to use are the responsibility of the user and should not be longer than 20 hours at 2°C to 8°C. Do not freeze.