

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1996
This medicine is dispensed with a doctor's prescription only

Skyrizi® 180 mg Skyrizi® 360 mg

Solution for injection in cartridge

The active ingredient and its concentration:

Skyrizi 180 mg:
Each cartridge contains 180 mg of risankizumab in 1.2 ml solution (150 mg/1 ml).
Skyrizi 360 mg:
Each cartridge contains 360 mg of risankizumab in 2.4 ml solution (150 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 360 mg 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 180 mg and Skyrizi 360 mg are 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

Skyrizi 180 mg and Skyrizi 360 mg:
This medicine contains 0.24 mg of polysorbate 20 in each 180 mg dose and 0.48 mg of polysorbate 20 in each 360 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 cartridge, 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 the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen of the medicine.

This medicine is given as an injection under your skin (called a 'subcutaneous injection'). The dosage and treatment regimen will be determined by the doctor only. Generally, the usual dosage is:

You will receive treatment with Skyrizi 600 mg preparation with a starting dose which will be given by your doctor or nurse through a drip in your arm (intravenous infusion).

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

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

Afterwards, you will receive Skyrizi as an injection under your skin.

Maintenance doses	How much?	When?	
Crohn's disease	1 st maintenance dose	360 mg	4 weeks after the last starting dose (at Week 12)
Further doses	360 mg	Every 8 weeks, after the 1 st maintenance dose	
Ulcerative colitis	1 st 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 1 st maintenance 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 you 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 have used more Skyrizi than you should or the dose has been given sooner than prescribed, talk to your doctor.

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

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

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 cartridge 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.

- If needed, you may also store the cartridge out of the refrigerator (up to a maximum of 25°C) for up to 24 hours.

- Keep the cartridge 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.
- Each on-body injector with cartridge is for single use only.
- 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. 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 yellow liquid in cartridge. The liquid may contain tiny white or clear particles. Each pack of Skyrizi 180 mg and Skyrizi 360 mg contains: 1 cartridge and 1 on-body injector.

- **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 numbers of the medicine in the National Drug Registry of the Ministry of Health:**
Skyrizi 360 mg: 172-09-37477
Skyrizi 180 mg: 179-61-38222

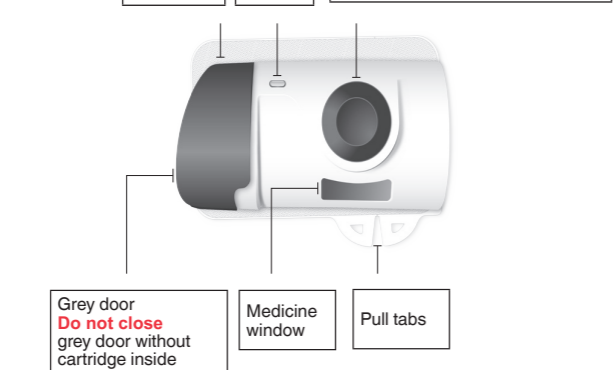
For additional information and the support program call-center call *6718

7. INSTRUCTIONS FOR USE

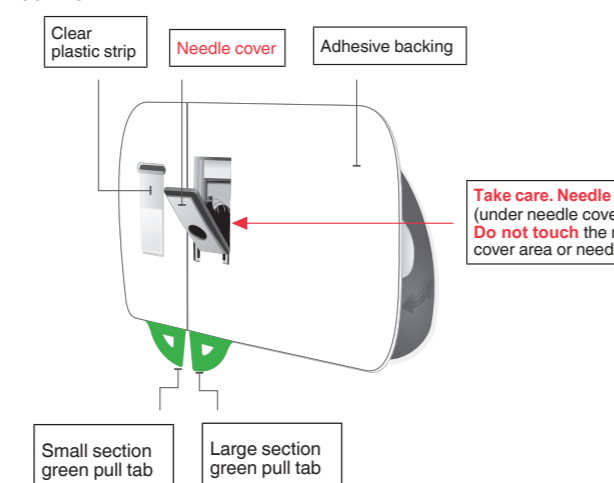
Please read all of section 7 before using Skyrizi

Skyrizi on-body injector

Front view

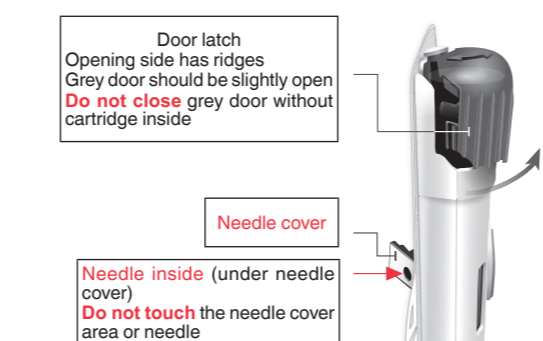


Back view

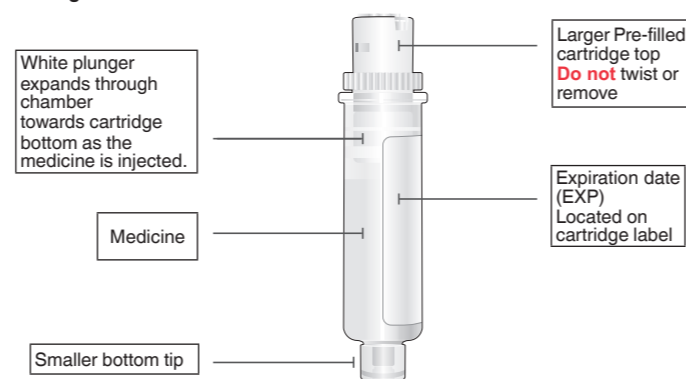


Small section green pull tab
Large section green pull tab

Side view



Cartridge



Important information to know before you inject Skyrizi

- Keep the cartridge in the original carton in order to protect from light.
- 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
- The single use on-body injector is designed for use with Skyrizi cartridge only
- 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 at least 45 up to 90 minutes before injecting
- Do not let the on-body injector get wet with water or any other liquids
- Do not touch the start button until you place the on-body injector loaded with the cartridge onto your skin and are ready to inject
 - You can only press the start button one time
- Physical activity should be limited during the injection process. Moderate physical activities can be done, such as walking, reaching and bending
- Do not delay in injecting the medicine after loading the cleaned cartridge into the on-body injector. Waiting will dry out the medicine and the on-body injector will not work afterwards
- 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 carton, cartridge or on-body injector
- Do not re-use the cartridge or the on-body injector

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 cartridge or on-body injector has been dropped or damaged
- if the carton perforations are broken
- if the white paper tray cover is broken or missing

Follow the steps below each time you use Skyrizi

STEP 1 – Get ready

1A

1B

1C

1D

1E

STEP 2 – Set up on-body injector

1F

2A

2B

2C

2D

2E

STEP 3 – Prepare to inject

3A

3B

3C

3D

STEP 4 – Inject Skyrizi

4A

4B

STEP 5 – Finish

5A

5B

Additional information

- On-body injector operating temperature range is 18°C to 28°C and relative humidity range 25% to 75%
- Altitude range is minus 400 metres to 3,200 metres

Symbol	Description of Symbol
	Keep dry
	Sterilized using ethylene oxide
	Do not re-use
	Do not use if package is damaged and consult instructions for use
	Date of manufacture
	Batch code
	Catalogue number
	Serial number
	Refer to instruction manual / booklet
	Type BF Applied Part
	MR Unsafe