

Medication Guide

SKYRIZI® (sky-RIZZ-ee) (risankizumab-rzaa)

injection, for subcutaneous or intravenous use

What is the most important information I should know about SKYRIZI?

SKYRIZI may cause serious side effects, including:

Serious allergic reactions. Stop using SKYRIZI and get emergency medical help right away if you get any of the following symptoms of a serious allergic reaction:

- fainting, dizziness, feeling lightheaded (low blood pressure)
- chest tightness
- swelling of your face, eyelids, lips, mouth, tongue, or throat
- skin rash, hives
- trouble breathing or throat tightness
- itching

Infections. SKYRIZI may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with SKYRIZI and may treat you for TB before you begin treatment with SKYRIZI if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with SKYRIZI. Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:

- fever, sweats, or chills
- muscle aches
- weight loss
- cough
- warm, red, or painful skin or sores on your body different from your psoriasis
- diarrhea or stomach pain
- shortness of breath
- burning when you urinate or urinating more often than normal
- blood in your mucus (phlegm)

See “What are the possible side effects of SKYRIZI?” for more information about side effects.

What is SKYRIZI?

SKYRIZI is a prescription medicine used to treat:

- moderate to severe plaque psoriasis in adults who may benefit from taking injections or pills (systemic therapy) or treatment using ultraviolet or UV light (phototherapy).
- active psoriatic arthritis in adults.
- moderate to severe Crohn’s disease in adults.

It is not known if SKYRIZI is safe and effective in children.

Who should not use SKYRIZI?

Do not use SKYRIZI if you are allergic to risankizumab-rzaa or any of the ingredients in SKYRIZI. See the end of this Medication Guide for a complete list of ingredients in SKYRIZI.

Before using SKYRIZI, tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section “What is the most important information I should know about SKYRIZI?”
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). Medicines that interact with the immune system may increase your risk of getting an infection after receiving live vaccines. You should avoid receiving live vaccines right before, during, or right after treatment with SKYRIZI. Tell your healthcare provider that you are taking SKYRIZI before receiving a vaccine.
- are pregnant or plan to become pregnant. It is not known if SKYRIZI can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if SKYRIZI passes into your breast milk.
- If you become pregnant while taking SKYRIZI, you are encouraged to enroll in the Pregnancy Registry. The purpose of the pregnancy registry is to collect information about the health of you and your baby. Talk to your healthcare provider or call 1-877-302-2161 to enroll in this registry.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use SKYRIZI?

See the detailed “Instructions for Use” that comes with SKYRIZI for information on how to prepare and inject a dose of SKYRIZI, and how to properly throw away (dispose of) a used SKYRIZI prefilled pen, prefilled syringe, or prefilled cartridge with on-body injector.

- Use SKYRIZI exactly as your healthcare provider tells you to use it.
- Your healthcare provider will tell you how much SKYRIZI is right for you and how often you should receive it.
- Before self-injecting with SKYRIZI prefilled pen, prefilled syringe, or prefilled cartridge with on-body injector, your healthcare provider should show you how to inject SKYRIZI.
- If you miss your SKYRIZI dose, inject a dose as soon as you remember. Then, take your next dose at your regular scheduled time. Call your healthcare provider if you are not sure what to do.
- If you inject more SKYRIZI than prescribed, call your healthcare provider right away.

Adults with plaque psoriasis or psoriatic arthritis will receive SKYRIZI as an injection under the skin (subcutaneous injection) using the prefilled pen or prefilled syringe.

Adults with Crohn’s disease will receive their starter doses with SKYRIZI through a vein in the arm (intravenous infusion) in a healthcare facility by a healthcare provider. After completing the starter doses, patients will receive SKYRIZI as an injection under the skin (subcutaneous injection) using the prefilled cartridge with on-body injector.

What are the possible side effects of SKYRIZI?

SKYRIZI may cause serious side effects including:

- **See “What is the most important information I should know about SKYRIZI?”**
- **Liver problems in Crohn’s disease.** A person with Crohn’s disease who received SKYRIZI by intravenous infusion (through a vein in the arm) developed changes in liver blood tests with a rash that led to hospitalization. Your healthcare provider will do blood tests to check your liver before, during, and up to 12 weeks of treatment with SKYRIZI. Your healthcare provider may stop treatment with SKYRIZI if you develop liver problems. Tell your healthcare provider right away if you notice any of the following symptoms:
 - unexplained rash
 - nausea
 - vomiting
 - stomach (abdominal) pain
 - tiredness (fatigue)
 - loss of appetite
 - yellowing of the skin and eyes (jaundice)
 - dark urine

The most common side effects of SKYRIZI in people treated for Crohn’s disease include:

- upper respiratory infections
- headache
- joint pain
- stomach (abdominal) pain
- injection site reactions
- low red blood cells (anemia)
- fever
- back pain
- urinary tract infection

The most common side effects of SKYRIZI in people treated for plaque psoriasis and psoriatic arthritis include:

- upper respiratory infections
- headache
- feeling tired
- injection site reactions
- fungal skin infections

These are not all the possible side effects of SKYRIZI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SKYRIZI?

- Store SKYRIZI in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Do not freeze SKYRIZI.
- Do not shake SKYRIZI.
- Keep SKYRIZI in the original carton to protect it from light.
- SKYRIZI is not made with natural rubber latex.

Keep SKYRIZI and all medicines out of the reach of children.

General information about the safe and effective use of SKYRIZI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use SKYRIZI for a condition for which it was not prescribed. Do not give SKYRIZI to other people,

even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about SKYRIZI that is written for health professionals.

What are the ingredients in SKYRIZI?

Active ingredient: risankizumab-rzaa.

SKYRIZI 75 mg/0.83 mL inactive ingredients: sodium succinate, polysorbate 20, sorbitol, succinic acid, and Water for Injection, USP.

SKYRIZI 150 mg/mL, 180 mg/1.2 mL, 360 mg/2.4 mL, and 600 mg/ 10 mL inactive ingredients: glacial acetic acid, polysorbate 20, sodium acetate, trehalose, and Water for Injection, USP.

Manufactured by: AbbVie Inc., North Chicago, IL 60064, U.S.A.

US License Number 1889

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For more information, call 1-866-SKYRIZI (1-866-759-7494) or go to www.SKYRIZI.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration
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