Skyrizi (risankizumab-rzaa)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Skyrizi
- **Generic name:** Risankizumab-rzaa
- **Pharmacological class:** Interleukin-23 antagonist
- **Strength and Formulation:** 75mg/0.83mL; per prefilled syringe; soln for SC inj; preservative-free
- **Manufacturer:** AbbVie
- **How supplied:** Single-dose prefilled syringes—2 (w. supplies)
- **Legal Classification:** Rx

Skyrizi


2 x 0.83 mL prefilled syringes
NDC 0074-2042-02
Skyrizi™
risankizumab-rzaa
Injection
75 mg/0.83 mL per Syringe
FOR SUBCUTANEOUS USE ONLY
FOR A 150 MG DOSE,
TWO 75 MG SYRINGES ARE REQUIRED,
INJECT ONE SYRINGE AFTER THE OTHER
ATTENTION PHARMACIST:
Each patient is required to receive the enclosed Medication Guide.
The entire carton is to be dispensed as a unit.
Return to pharmacy if syringe tray seal is broken or missing.
www.SKYRIZI.com
TO OPEN
Rx only
abbvie

Indication

- Moderate to severe **plaque psoriasis** in adults who are candidates for systemic therapy or phototherapy

Dosage & Administration

- Give by SC inj in abdomen, thighs, or upper arm
- ≥18yrs: 150mg (two 75mg injections) by SC inj at Weeks 0 and 4, then every 12 weeks thereafter

Considerations for Special Populations

- **Pregnancy:** Limited available data
- **Nursing mothers:** No data on the presence of risankizumab-rzaa in human milk, the effects on the breastfed infant, or the effects on milk production
- **Pediatric:** <18yrs: not established
- **Elderly:** Number of patients aged 65 years and older was not sufficient to determine whether they respond differently from younger subjects

Warnings/Precautions

- Use under physician supervision and guidance
- May increase risk of **infections**
- Chronic or history of recurrent infection: consider the risks and benefits
- If a serious infection develops or is not responding to standard therapy, monitor closely and discontinue Skyrizi until resolves

Warnings/Precautions

- Evaluate for **tuberculosis** (TB) infection prior to initiating
- History of latent or active TB (without confirmed adequate treatment); consider anti-TB therapy prior to initiation
- Monitor for signs/symptoms of active TB during and after therapy
- Patients with active TB infection: do not initiate
- Consider completion of all age appropriate immunizations according to current guidelines before starting therapy

Interactions

- Avoid use of **live vaccines**

Adverse Reactions

- **Most common** (≥ 1%): upper respiratory infections, headache, fatigue, injection site reactions, tinea infections

Mechanism of Action

- Risankizumab-rzaa, a humanized immunoglobulin G1 (IgG1) monoclonal antibody, works by selectively binding to the p19 subunit of human interleukin 23 (IL-23) cytokine and inhibiting its interaction with the IL-23 receptor
- IL-23, a naturally occurring cytokine, is involved in inflammatory and immune responses
- By binding to IL-23, risankizumab-rzaa inhibits the release of pro-inflammatory cytokines and chemokines

Clinical Studies

- The efficacy and safety of Skyrizi were evaluated in 4 double-blind studies (ULTIMMA-1, ULTIMMA-2, IMMHANCE, and IMMVENT) involving a total of 2,109 adults with moderate to severe plaque psoriasis who had a body surface area (BSA) involvement of ≥10%, a static Physician's Global Assessment (sPGA) score of ≥3 ("moderate") in the overall assessment (plaque thickness/induration, erythema, and scaling) of psoriasis on a severity scale of 0 to 4, and a Psoriasis Area and Severity Index (PASI) score ≥12

Clinical Studies

- ULTIMMA-1 and ULTIMMA-2 assessed the response of Skyrizi 150mg compared with placebo at Week 16
- The coprimary endpoints were the proportion of patients who achieved an sPGA score of 0 (“clear”) or 1 (“almost clear”) and the proportion of patients who achieved at least a 90% reduction from baseline PASI (PASI 90)

Clinical Studies

- Results from **ULTIMMA-1** showed that 88% of patients treated with Skyrizi achieved sPGA 0 or 1, and 75% achieved PASI 90 at Week 16 compared with 8% and 5% in the placebo group, respectively
- In **ULTIMMA-2**, 84% of patients treated with Skyrizi achieved sPGA 0 or 1 compared with 5% in the placebo group
- In Skyrizi-treated patients, 75% achieved PASI 90 vs 2% of placebo-treated patients

Clinical Studies

- Secondary endpoints including the proportion of patients who achieved PASI 100, sPGA 0, and Psoriasis Symptom Scale (PSS) 0 at Week 16
- In **ULTIMMA-1**, 36% in the Skyrizi group achieved PASI 100 and 37% achieved sPGA 0 compared with 0% and 2% in placebo, respectively
- In **ULTIMMA-2**, both PASI 100 and sPGA 0 were achieved in 51% of patients treated with Skyrizi vs 2% and 3% in placebo-treated patients, respectively
- In both studies, about 30% of Skyrizi patients achieved PSS 0 (“none”) at Week 16 vs 1% of placebo patients

Clinical Studies

- The **IMMHANCE** study also compared the response of Skyrizi 150mg to placebo at Week 16
- Similar to the results from the previous studies, Skyrizi was shown to be superior to placebo on the coprimary endpoints of sPGA 0 or 1 and PASI 90
- At Week 16, 84% of patients treated with Skyrizi achieved sPGA 0 or 1 compared with 7% of placebo-treated patients
- PASI 90 was achieved in 73% of patients in the Skyrizi group vs 2% of the placebo group
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/skyrizi/