Pr Skyrizi™

(risankizumab) injection

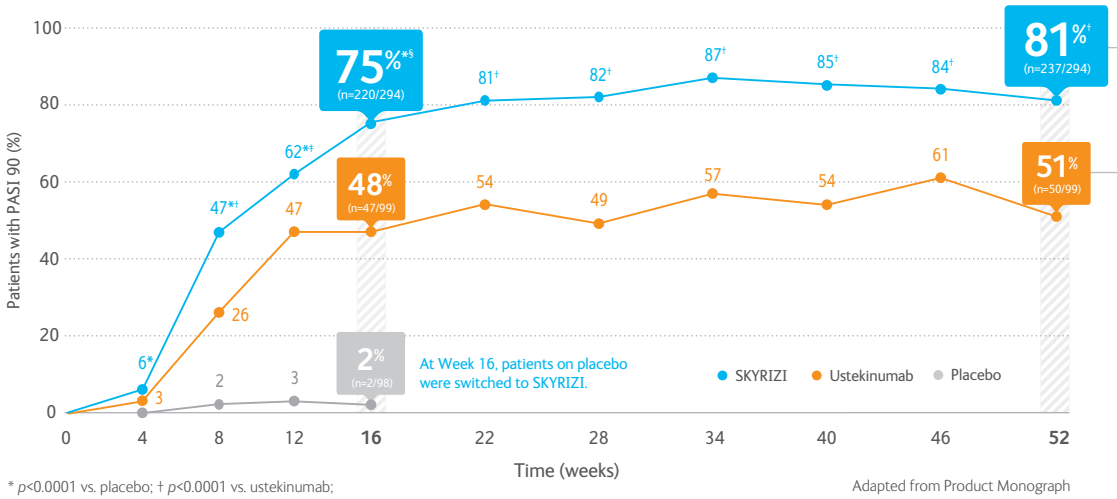
Now available

SKYRIZI (risankizumab injection) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

SKYRIZI – Significantly more patients achieved PASI 90 vs. ustekinumab at Week 52 (secondary endpoint)[1,2]

PASI 90 and sPGA of 0/1 at Week 16 vs. placebo were co-primary endpoints. Secondary endpoints included PASI 90 at Weeks 16 and 52 vs. ustekinumab.

ULTIMMA-2 study: Proportions of patients (non-responder imputation) that achieved PASI 90



30% more patients achieved PASI 90 vs. ustekinumab (treatment difference: 30.2%; 95% CI: 19.6, 40.9)

* $p<0.0001$ vs. placebo; † $p<0.0001$ vs. ustekinumab; ‡ $p=0.0107$ vs. ustekinumab; § Treatment difference: 72.5% (95% CI: 66.8, 78.2) vs. placebo; 27.6% (95% CI: 16.7, 38.5) vs. ustekinumab.

Adapted from Product Monograph and Gordon KB, *et al.*[1,2‖]

ULTIMMA-1 study

- **Proportions of patients that achieved PASI 90**[1‖]
  - **Week 16**: 75.3% (n=229/304) with SKYRIZI vs. 42.0% (n=42/100) with ustekinumab (secondary endpoint) and 4.9% (n=5/102) with placebo (co-primary endpoint; treatment difference vs. placebo and ustekinumab: 70.3% [95% CI: 64.0, 76.7] and 33.5% [95% CI: 22.7, 44.3], respectively)
  - **Week 52**: 81.9% (n=249/304) with SKYRIZI vs. 44.0% (n=44/100) with ustekinumab (secondary endpoint; treatment difference vs. ustekinumab: 38.3% [95% CI: 27.9, 48.6])
- **At Week 16, 87.8% (n=267/304) of patients on SKYRIZI achieved sPGA of 0/1 vs. 7.8% (n=8/102) of patients on placebo** ($p<0.001$; co-primary endpoint)[1‖]

At Week 16, 83.7% (n=246/294) of patients on SKYRIZI achieved sPGA of 0/1 vs. 5.1% (n=5/98) of patients on placebo ($p<0.001$; co-primary endpoint)[1‖]

Convenient every-12-week dosing following initial doses at Week 0 and Week 4[1]

Maintenance dosing

Adapted from Product Monograph[1]

The recommended dose is 150 mg (two 75 mg injections) administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter.[1]

Dosing considerations[1]

- SKYRIZI is intended for use under the guidance and supervision of a physician.
- Patients may self-inject SKYRIZI if their physician determines that it is appropriate and with medical follow-up, as necessary, after proper training in subcutaneous injection technique.

PASI: Psoriasis Area and Severity Index; sPGA: static Physician Global Assessment.

‖ The efficacy and safety profile of SKYRIZI were assessed in 997 patients with moderate to severe plaque psoriasis in two multicentre, randomized, double-blind studies (ULTIMMA-1 and ULTIMMA-2). 598 patients were randomized to SKYRIZI 150 mg. 199 to ustekinumab 45 mg (≤100 kg body weight) or 90 mg (>100 kg body weight) and 200 to placebo. Patients received treatment at Week 0, Week 4, and every 12 weeks thereafter.

Storing SKYRIZI[1]

Store in a refrigerator between 2 to 8°C (36 to 46°F). Do not freeze.

Keep the pre-filled syringes in the outer carton in order to protect from light.

Generally well-established safety profile[1]

Adverse reactions occurring in ≥1% of patients on SKYRIZI through Week 16

	SKYRIZI n=1,306	Placebo n=300	Ustekinumab n=199
General Disorders and Administration Site Conditions			
Fatigue*	2.5%	1.0%	2.5%
Injection site reactions†	1.5%	1.0%	2.5%
Infections and Infestations			
Upper respiratory tract infections‡	13.0%	9.7%	12.6%
Urinary tract infection	1.1%	0.7%	2.5%
Tinea infections§	1.1%	0.3%	0%
Nervous System Disorders			
Headache‖	3.5%	2.0%	3.5%
Skin and Subcutaneous Tissue Disorders			
Pruritus	1.5%	1.3%	1.5%

Adapted from Product Monograph[1]

- Most of the most frequently (≥10%) reported adverse drug reactions were mild or moderate in severity.
- Serious adverse events were reported in 2.4% of SKYRIZI-treated patients and 4.0% of placebo-treated patients through 16 weeks.

* Includes: fatigue, asthenia
† Includes: injection site bruising, erythema, extravasation, hematoma, hemorrhage, infection, inflammation, irritation, pain, pruritus, reaction, swelling, warmth
‡ Includes: respiratory tract infection (viral, bacterial, or unspecified), sinusitis (including acute), rhinitis, nasopharyngitis, pharyngitis (including viral), tonsillitis
§ Includes: tinea pedis, tinea cruris, body tinea, tinea versicolour, tinea manuum, tinea infection
‖ Includes: headache, tension headache, sinus headache, cervicogenic headache

Drug interactions[1]

SKYRIZI is not expected to undergo metabolism by hepatic enzymes or renal elimination. Drug interactions between SKYRIZI and substrates/inhibitors/inducers of drug metabolizing enzymes are not expected.

Drug-drug interactions:

- Live vaccines should not be given while a patient is undergoing therapy with SKYRIZI.
- The safety and efficacy of SKYRIZI in combination with immunosuppressant drugs, including biologics, or with phototherapy, have not been evaluated.
- Interactions with CYP450 substrates:
  - The formation of cytochrome P450 (CYP) enzymes can be altered by increased levels of certain cytokines during chronic inflammation.
  - The exposure of caffeine (CYP1A2 substrate), warfarin (CYP2C9 substrate), omeprazole (CYP2C19 substrate), metoprolol (CYP2D6 substrate) and midazolam (CYP3A substrate) following administration of risankizumab injection were comparable to their exposures prior to risankizumab injection, indicating no interactions through these enzymes.
  - Population pharmacokinetic analyses indicated that risankizumab exposure was not impacted by concomitant medications (metformin, atorvastatin, lisinopril, amlodipine, ibuprofen, acetylsalicylate and levothyroxine) used by some patients with plaque psoriasis during the clinical studies.

Drug-food interactions: Interactions with food have not been studied.

Drug-herb interactions: Interactions with herbal products have not been studied.

Drug-laboratory test interactions: Interactions with laboratory tests have not been studied.

Clinical use:

Efficacy and safety in pediatric population (<18 years of age) have not been evaluated. Limited data available for geriatrics (≥65 years of age).

Relevant warnings and precautions:

- Infections including tuberculosis
- Vaccinations
- Hypersensitivity
- Pregnant or nursing women
- Women of childbearing potential

For more information:

Please consult the Product Monograph at www.abbvie.ca/content/dam/abbviecorp/ca/en/docs/SKYRIZI_PM_EN.pdf for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling us at 1-888-704-8271.

References: 1. SKYRIZI Product Monograph. AbbVie Corporation. April 17, 2019. **2.** Gordon KB, *et al.* Efficacy and safety of risankizumab in moderate-to-severe plaque psoriasis (ULTIMMA-1 and ULTIMMA-2): results from two double-blind, randomised, placebo-controlled and ustekinumab-controlled phase 3 trials. *Lancet* 2018;392(10148):650-61.