Skyrizi®
(risankizumab)

NOW APPROVED

for adults with PSORIATIC ARTHRITIS[1]

SKYRIZI:
An IL-23/p19 inhibitor[2-7]

Indications[1]

Plaque psoriasis: SKYRIZI (risankizumab) is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Psoriatic arthritis: SKYRIZI (risankizumab), alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more DMARDs.

DMARD: disease-modifying antirheumatic drug; **IL**: interleukin; **MTX**: methotrexate.

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Please see Important Safety Information on page 7.

SKYRIZI® (risankizumab) is approved for adults with moderate to severe PsO *AND*

NOW APPROVED FOR ADULTS WITH ACTIVE PsA

DURABILITY

Nothing less than the opportunity for durable, complete skin clearance[1,8]

PsO >

SIMPLICITY

Nothing more than 4 injections per year after initiation doses[1]*

SIMPLICITY data >

SAFETY

Favorable safety profile consistent for both PsO and PsA[1,9,10]

SAFETY data >

Durable control of PsA signs and symptoms could mean everything for your patients[1]

PsA >

*SKYRIZI maintenance dosing 150 mg (one 150-mg subcutaneous injection) every 12 weeks following a starter dose at Week 0 and Week 4.

SKYRIZI FOR PsO:

DEMONSTRATED SUPERIORITY

at achieving durable, complete skin clearance versus 3 agents in different biologic classes

DURABLE AT WEEK 52

Superior to ustekinumab

at Week 16 and Week 52: UltIMMa pivotal trials (P<0.001)[1,8]

- **2x the percentage of patients achieved PASI 100** at Week 16 and Week 52 with SKYRIZI (UltIMMa-2)
- **60% of patients achieved PASI 100** at Week 52 with SKYRIZI vs 30% ustekinumab
  - Week 16: 51% vs 24%, respectively
- **81% of patients achieved PASI 90** at Week 52 with SKYRIZI vs 51% ustekinumab
  - Week 16: 75% vs 47%, respectively†

Superior to secukinumab

at Week 52: IMMerge assessor-blinded Phase 3b trial (P<0.001)[11,12]

- **26%** **absolute difference in patients achieving PASI 100** at Week 52 with SKYRIZI (95% CI: adjusted difference; 15.9, 36.5)
  - 66% SKYRIZI vs 40% secukinumab
- **30%** **absolute difference in patients achieving PASI 90†** at Week 52 with SKYRIZI (95% CI: adjusted difference; 20.8, 38.8)
  - 87% SKYRIZI vs 57% secukinumab

PASI 90 at Week 16 (noninferiority)†: SKYRIZI 74% vs secukinumab 66%

DURABLE AT WEEK 44

Superior to adalimumab

at Week 16 and Week 44: IMMvent pivotal trial (P<0.001)[13]

- **40% of patients achieved PASI 100** at Week 16 with SKYRIZI vs 23% adalimumab
  - 72% vs 47% achieved PASI 90†, respectively

Among adalimumab intermediate responders (PASI 50 to <PASI 90) who were rerandomized at Week 16:

- Week 44: 40% SKYRIZI vs 7% adalimumab achieved PASI 100
- Week 44: 66% SKYRIZI vs 21% adalimumab achieved PASI 90†

STUDY DESIGNS >

† **Primary endpoint.** Note: Some studies were designed with primary endpoints in two parts (Part A and Part B), per protocol. All other endpoints were ranked secondary.

PASI: Psoriasis Area and Severity Index; **PsA:** psoriatic arthritis; **PsO:** plaque psoriasis.

Please see Indications and Important Safety Information on page 7.

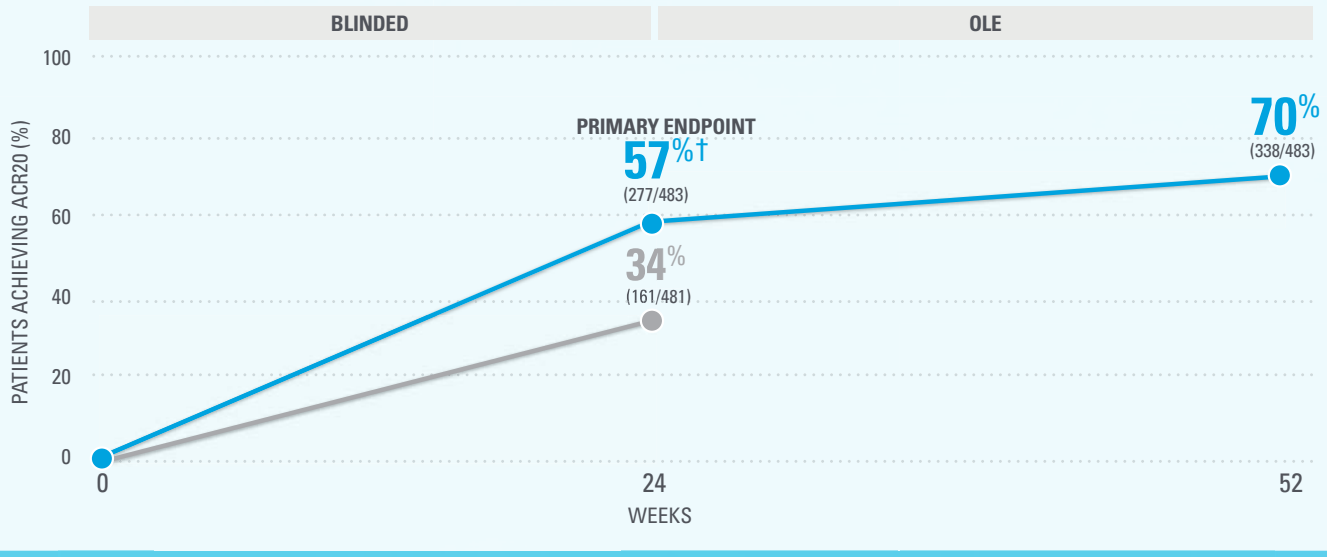
Skyrizi® (risankizumab)

DURABLE CONTROL OF PsA SIGNS AND SYMPTOMS

could mean everything for your patients

In KEEPsAKE-1:

~7 OUT OF 10 PATIENTS ACHIEVED ACR20 AT WEEK 52 (NRI)[1,14*]



SKYRIZI dose was 150 mg administered subcutaneously at Week 0, Week 4, and every 12 weeks thereafter. Starting from Week 28, all subjects received SKYRIZI every 12 weeks.
Summarized from KEEPsAKE-1 (bio-naïve population).

Primary endpoint[1]
- ACR20 response at Week 24 (%) vs placebo

Ranked secondary endpoints[1]
- ACR20 response at Week 16 (%)
- Resolution of enthesitis at Week 24 (%) (pooled)
- Resolution of dactylitis at Week 24 (%) (pooled)
- Minimal disease activity at Week 24 (%)

*65.5% of subjects from KEEPsAKE-1 taking placebo and 65% of SKYRIZI patients were receiving concomitant MTX. 10.2% of patients taking placebo and 10.7% of SKYRIZI patients were receiving concomitant nonbiologic DMARDs other than MTX.[1]

†$P \leq 0.001$.[1]

KEEPsAKE-1/2 STUDY DESIGN >

4 INJECTIONS PER YEAR

after initiation doses for both PsO and PsA patients[1‡]

NO DOSE ADJUSTMENT required regardless of baseline characteristics, including BMI and weight[1,15-17§]

INITIATION	12 WEEKS	12 WEEKS	12 WEEKS	12 WEEKS
1 INJECTION WEEKS 0 AND 4	1 INJECTION WEEK 16	1 INJECTION WEEK 28	1 INJECTION WEEK 40	1 INJECTION WEEK 52

SKYRIZI is dosed 150 mg (one 150-mg subcutaneous injection) at Week 0, Week 4, and every 12 weeks thereafter[1]

- 1 injection/dose for both the SKYRIZI prefilled pen and prefilled syringe
- Consideration should be given to discontinuing treatment in patients who have shown no response after 16 weeks of treatment. Some PsO patients with initial partial response may subsequently improve with continued treatment beyond 16 weeks.

‡Maintenance dosing (1 injection/dose) every 12 weeks following a starter dose at Week 0 and Week 4. If a dose is missed, the dose should be administered as soon as possible. Thereafter, dosing should be resumed at the regular scheduled time.

§Risankizumab clearance and volume of distribution increase as body weight increases, which may result in reduced efficacy in subjects with high body weight (>130 kg). However, this observation is based on a limited number of subjects.

ACR: American College of Rheumatology; **BMI**: body mass index; **DMARD**: disease-modifying antirheumatic drug; **MTX**: methotrexate; **NRI**: nonresponder imputation; **OLE**: open-label extension; **PsA**: psoriatic arthritis; **PsO**: plaque psoriasis.

Please see Indications and Important Safety Information on page 7.

Skyrizi® (risankizumab)

A FAVORABLE SAFETY PROFILE

Adverse events at Week 16 as reported across four Phase 3 PsO trials in 2,109 patients[1,8]

	UltIMMa-1[8,18] (N=506)			UltIMMa-2[8,18] (N=491)			IMMvent[13] (N=605)		IMMhance[19,20] (N=507)	
	SKYRIZI (n=304)	PBO (n=102)	UST (n=100)	SKYRIZI (n=294)	PBO (n=98)	UST (n=99)	SKYRIZI (n=301)	ADA (n=304)	SKYRIZI (n=407)	PBO (n=100)
Any adverse event	49.7%	51.0%	50.0%	45.6%	45.9%	53.5%	55.8%	56.9%	45.5%	48.0%
Serious adverse events	2.3%	2.9%	8.0%	2.0%	1.0%	3.0%	3.3%	3.0%	2.0%	8.0%
Any adjudicated MACE	0	0	0	0	0	0	0.3%†	0	0	1.0%‡
Any serious infection	0.3%	0	3.0%	1.0%	0	1.0%	0.3%	0.3%	0	1.0%
Any malignant tumor	0.3%	1.0%	0	0.3%	0	0	0.3%	0.3%	0.7%§	0
Deaths (incl. non–treatment-emergent)	0	0	0	0.3%*	0	0	0.3%†	0.7%	0	0

*UltIMMa: One non–treatment-emergent death of unknown cause on study Day 189 that occurred 161 days after the last dose of study drug.

†IMMvent: One patient with acute myocardial infarction on study Day 73 (event was not considered to be study drug related by investigator).

‡IMMhance: One patient with stroke reported as ischemic stroke on study Day 95.

§IMMhance: One patient with esophageal carcinoma reported on study Day 16, with patient experiencing 40 lbs weight loss 6 months prior to study participation; one patient with malignant melanoma in situ reported on study Day 102, study drug was not interrupted; one patient with a cutaneous squamous cell carcinoma reported on study Day 89, study drug not interrupted.

STUDY DESIGNS >

PsA SAFETY PROFILE CONSISTENT WITH PsO

No new safety signals observed[1]

	KEEPsAKE-1[1,9] Week 24		KEEPsAKE-2[1,10] Week 24	
Events (E/100 PYs)	SKYRIZI (N=483)	PBO (N=481)	SKYRIZI (N=224)	PBO (N=219)
Any TEAE	195 (40.4)	186 (38.7)	124 (55.4)	120 (54.8)
COVID-19-related TEAE	1 (0.2)	2 (0.4)	1 (0.4)††	0
Serious TEAE	12 (2.5)	18 (3.7)	9 (4.0)	12 (5.5)
Severe TEAE	10 (2.1)	9 (1.9)	6 (2.7)	7 (3.2)
TEAE leading to discontinuation of study drug	4 (0.8)	4 (0.8)	2 (0.9)	5 (2.3)
Death	1 (0.2)‖	0	0	0
Serious infection	5 (1.0)¶	6 (1.2)¶	2 (0.9)‡‡	5 (2.3)
Herpes zoster	2 (0.4)#	1 (0.2)#	0	1 (0.5)
Malignancy	0	2 (0.4)	1 (0.4)	1 (0.5)
Injection site reaction	3 (0.6)**	0	3 (1.3)§§	1 (0.5)

KEEPsAKE-1/2 STUDY DESIGN >

SKYRIZI dose was 150 mg administered subcutaneously at Week 0, Week 4, and every 12 weeks thereafter in KEEPsAKE-1/2.

‖81-year-old male patient with dementia who was hospitalized for pneumonia and subsequently developed urosepsis resulting in death.

¶SKYRIZI: urosepsis (1 patient, resulting in death), cellulitis (1 patient), gastroenteritis (1 patient), COVID-19 pneumonia (1 patient), viral upper respiratory tract infection leading to pneumonia (1 patient); Placebo: pneumonia (2 patients), oral bacterial infection (1 patient), dysentery (1 patient), appendicitis (1 patient), cellulitis (1 patient).

#All nonserious, resolved with oral antiviral agents, and did not result in discontinuation of study drug.

**All nonserious and did not result in discontinuation of study drug.

††Mild, not related to study drug.

‡‡Abscess/cellulitis (1 patient), gastroenteritis (1 patient).

§§All nonserious and did not result in discontinuation of study drug.

ADA: adalimumab; **MACE**: major adverse cardiovascular event; **PBO**: placebo; **PsA**: psoriatic arthritis; **PsO**: plaque psoriasis; **TEAE**: treatment-emergent adverse event; **UST**: ustekinumab.

Please see Indications and Important Safety Information on page 7.

Skyrizi® (risankizumab)

AEs OF SPECIAL INTEREST FOR PsA STABLE BETWEEN WEEK 24 AND WEEK 52[14]

Events (E/100 PYs)	KEEPsAKE-1[14]		KEEPsAKE-2[14]	
	Week 24 N=483 (PYs=224.1)	**Week 52*** N=481 (PYs=958.1)	**Week 24** N=224 (PYs=104.3)	**Week 52*** N=419 (PYs=509.7)
Adjudicated major adverse cardiovascular event (MACE)	0	0	1 (1.0)	3 (0.6)
Serious infections	6 (2.7)	27 (2.8)†	3 (2.9)	10 (2.0)
Herpes zoster	2 (0.9)	4 (0.4)	0	3 (0.6)
Opportunistic infection excluding tuberculosis and herpes zoster	0	1 (0.1)	0	1 (0.2)
Malignant tumors	0	6 (0.6)	1 (1.0)	11 (2.2)
Nonmelanoma skin cancer (NMSC)	0	2 (0.2)	0	9 (0.8)
Deaths‡	1 (0.4)	2 (0.2)	0	0
Active tuberculosis	0	0	0	0
Anaphylactic reactions	0	0	0	0

SKYRIZI dose was 150 mg administered subcutaneously at Week 0, Week 4, and every 12 weeks thereafter in KEEPsAKE-1/2.

*Safety reported through data cutoff date (April 19, 2021), which includes data through Week 52. Data includes all patients who received SKYRIZI 150 mg, including those who started on SKYRIZI 150 mg at randomization and who switched from placebo to SKYRIZI 150 mg after Week 24.

†10 of the 27 events were cases of COVID-19.

‡An 81-year-old patient randomized to SKYRIZI died of urosepsis on Day 96, and a 41-year-old patient randomized to SKYRIZI experienced sudden death on Day 502.

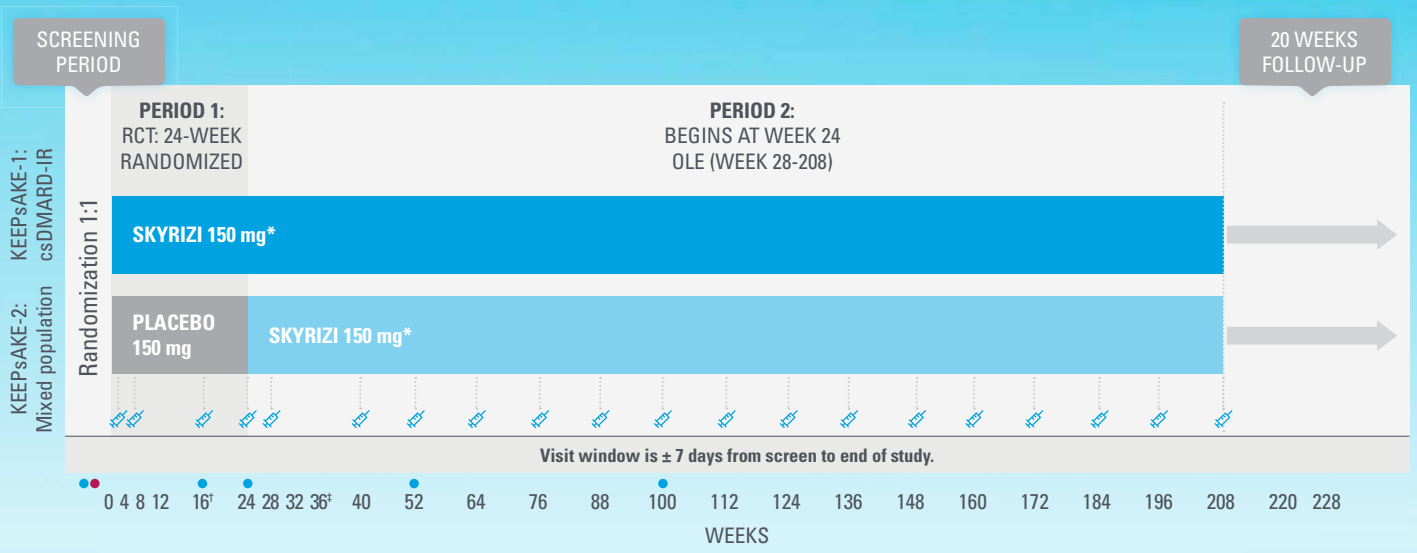
Please see Indications and Important Safety Information on page 7.

Skyrizi® (risankizumab)

KEEPsAKE-1 and KEEPsAKE-2:

study design[1,14]

Two randomized, double-blind, placebo-controlled studies assessing the safety and efficacy of 1,407 patients (964 in KEEPsAKE-1 and 443 in KEEPsAKE-2) ≥18 years old with active PsA.



Primary endpoint	Ranked secondary endpoints[1]
• ACR20 response at Week 24 (%) vs placebo	• ACR20 response at Week 16 (%) • Resolution of enthesitis at Week 24 (%) (pooled) • Resolution of dactylitis at Week 24 (%) (pooled) • Minimal disease activity at Week 24 (%)

=dose

*SKYRIZI dose was 150 mg administered subcutaneously at Week 0, Week 4, and every 12 weeks thereafter in KEEPsAKE-1/2.
Bilateral radiographs of hand and feet: • KEEPsAKE-1. • KEEPsAKE-2.
Mixed population=50% csDMARD-IR, 50% Bio-IR population.

†At Week 16, subjects classified as nonresponders (defined as not achieving at least a 20% improvement in either or both tender joint count and swollen joint count at both Week 12 and Week 16 compared to baseline) had the option to add or modify rescue concomitant medications/therapy.
‡Starting at Week 36, subjects classified as nonresponders were discontinued from study drug.

Study design[1]

In the two randomized, double-blind, placebo-controlled KEEPsAKE-1 and KEEPsAKE-2 studies, patients had a diagnosis of PsA ≥6 months based on Classification Criteria for Psoriatic Arthritis (CASPAR), a median duration of PsA of 4.9 years at baseline, ≥5 tender joints and ≥5 swollen joints, and active plaque psoriasis or nail psoriasis at baseline. 55.9% of subjects had ≥3% body surface area with active plaque psoriasis. 63.4% and 27.9% of subjects had enthesitis and dactylitis, respectively.

In KEEPsAKE-1, all subjects had a previous inadequate response or intolerance to nonbiologic DMARD therapy and were biologic naïve. In KEEPsAKE-2, 53.5% of subjects had a previous inadequate response or intolerance to nonbiologic DMARD therapy and 46.5% of subjects had a previous inadequate response or intolerance to biologic therapy.

In both studies, subjects were randomized to receive SKYRIZI 150 mg subcutaneously or placebo at Weeks 0, 4, and 16. Starting from Week 28, all subjects received SKYRIZI every 12 weeks. Both studies include a long-term extension for up to an additional 204 weeks. 59.6% of subjects from both studies were receiving concomitant MTX, 11.6% were receiving concomitant nonbiologic DMARDs other than MTX, and 28.9% were receiving SKYRIZI monotherapy. SKYRIZI was dosed 150 mg subcutaneously at Week 0, Week 4, and every 12 weeks thereafter.

ACR: American College of Rheumatology; **Bio-IR**: biologic inadequate response; **csDMARD-IR**: conventional synthetic disease-modifying antirheumatic drug inadequate response; **OLE**: open-label extension; **RCT**: randomized controlled trial; **PsA**: psoriatic arthritis.

Please see Indications and Important Safety Information on page 7.

Skyrizi® (risankizumab)

STUDY DESIGNS

UltIMMa-1 (N=506) and UltIMMa-2 (N=491) pivotal trials[8,18]

Replicate Phase 3, randomized, double-blind, placebo-controlled and active comparator-controlled trials done at 139 sites in Australia, Austria, Belgium, Canada, Czech Republic, France, Germany, Japan, Mexico, Poland, Portugal, South Korea, Spain, and the United States. Eligible patients were 18 years or older, with moderate to severe chronic plaque psoriasis. In each study, patients were stratified by weight and previous exposure to TNF inhibitor and randomly assigned (3:1:1) by use of interactive response technology to receive 150 mg risankizumab, 45 mg or 90 mg ustekinumab (weight-based per label), or placebo.

Following the 16-week double-blind treatment period (Part A), patients initially assigned to placebo switched to 150 mg risankizumab at Week 16; other patients continued their originally randomized treatment (Part B, double-blind, Weeks 16–52).

Study drug was administered subcutaneously at Weeks 0 and 4 during Part A and at Weeks 16, 28, and 40 during Part B.

Co-primary endpoints were proportions of patients achieving a 90% improvement in the Psoriasis Area Severity Index (PASI 90) and a static Physician's Global Assessment (sPGA) score of 0 or 1 at Week 16 (nonresponder imputation).

All efficacy analyses were done in the ITT population.

IMMerge study design[11,12]

A Phase 3b, multicenter, randomized, open-label, efficacy assessor-blinded, active-comparator study designed to evaluate the safety and efficacy of SKYRIZI compared to secukinumab in adult patients with moderate to severe plaque psoriasis. Patients were randomized 1:1 to SKYRIZI (n=164) (150 mg), given as two 75-mg subcutaneous injections at baseline, 4 weeks later, and every 12 weeks thereafter, or secukinumab (n=163) (300 mg) given as two 150-mg subcutaneous injections, at baseline, Weeks 1, 2, 3, and 4, and then every 4 weeks thereafter. Safety was assessed in all patients.

Data analysis: Missing data were imputed as NRI for all primary and ranked secondary endpoints.

Primary endpoints:
- **PASI 90 at Week 52 (superiority):** SKYRIZI 87% vs secukinumab 57% (P<0.001)
- **PASI 90 at Week 16 (noninferiority):** SKYRIZI 74% vs secukinumab 66%

Ranked secondary endpoints:
- PASI 100 at Week 52 (P<0.001), PASI 75 at Week 52 (P<0.001), sPGA 0/1 at Week 52 (P<0.001)

IMMvent pivotal Phase 3 study design[13]

A 44-week, randomized comparative study vs adalimumab in patients with moderate to severe chronic plaque psoriasis (N=605). IMMvent was powered to show superiority of SKYRIZI over adalimumab in achieving:
- PASI 90 response and sPGA scores of clear or almost clear at Week 16
- PASI 90 response at Week 44 after switching from adalimumab to SKYRIZI vs continuing adalimumab among patients with a ≥PASI 50 to <PASI 90 response after 16 weeks of adalimumab treatment.

Primary endpoint after rerandomization:
PASI 90 at Week 44 (rerandomized patients)

Secondary endpoints:
- PASI 75 at Week 16
- PASI 100 at Weeks 16 and 44 (rerandomized patients only at Week 44)

Part A (baseline to Week 16): Patients received either SKYRIZI (150 mg at Weeks 0 and 4) or adalimumab (80 mg at baseline, 40 mg at Week 1, and then once every 2 weeks). Study drug was administered subcutaneously.

Part B (Weeks 16 to 44): The SKYRIZI group continued on treatment (150 mg at Weeks 16 and 28). For the adalimumab group, treatment regimen was dependent on the level of PASI response:
- PASI <50 switched to SKYRIZI
- PASI 50 to <PASI 90 (rerandomized to either SKYRIZI or adalimumab)
- ≥PASI 90 continued with adalimumab.

Adalimumab patients who switched to risankizumab in Part B were dosed at Weeks 16, 20, and 32.

<<LOCAL MARKETS TO UPDATE WITH LOCAL PRESCRIBING INFORMATION>>

Important Safety Information

Indications[1]

Plaque psoriasis: SKYRIZI (risankizumab) is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Psoriatic arthritis: SKYRIZI (risankizumab), alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more DMARDs.

Safety Information[1]

SKYRIZI is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients. SKYRIZI may increase the risk of infection. In patients with a chronic infection, a history of recurrent infection, or known risk factors for infection, SKYRIZI should be used with caution. Treatment with SKYRIZI should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

Prior to initiating treatment with SKYRIZI, patients should be evaluated for tuberculosis (TB) infection. Patients receiving SKYRIZI should be monitored for signs and symptoms of active TB. Anti-TB therapy should be considered prior to initiating SKYRIZI in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed.

Prior to initiating therapy with SKYRIZI, completion of all appropriate immunisations should be considered according to current immunisation guidelines. If a patient has received live vaccination (viral or bacterial), it is recommended to wait at least 4 weeks prior to starting treatment with SKYRIZI. Patients treated with SKYRIZI should not receive live vaccines during treatment and for at least 21 weeks after treatment.

The most frequently reported adverse reactions were upper respiratory infections. Commonly (≥1/100 to <1/10) reported adverse reactions included tinea infections, headache, pruritus, fatigue and injection site reactions.

Please see the accompanying product labeling or complete safety information.

Adverse events should be reported.
Reporting forms and information can be found atwww.XXXXXXXXXXXXXXXXX.
Adverse events should also be reported to AbbVie at XXXX XXX XXXX.

DMARD: disease-modifying antirheumatic drug; **ITT**: intent-to-treat; **MTX**: methotrexate; **NRI**: nonresponder imputation; **TNF**: tumor necrosis factor.

Skyrizi® (risankizumab)

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