

PRESCRIBING INFORMATION (PI)

SKYRIZI™ ▼ (risankizumab) 75 mg solution for injection in pre-filled syringe

Refer to Summary of Product Characteristics (SmPC) for full information before prescribing.

PRESENTATION: Each pre-filled syringe contains 75 mg risankizumab in 0.83 ml solution.

INDICATION: For treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

DOSAGE AND ADMINISTRATION: Intended for use under guidance and supervision of a physician experienced in diagnosis and treatment of psoriasis. **Dosage:** The recommended dose of Skyrizi is 150 mg (two 75 mg injections) by subcutaneous injection at weeks 0, 4, and every 12 weeks thereafter. Consider discontinuation of treatment in patients showing no response after 16 weeks of treatment. Some patients with initial partial response may subsequently improve with continued treatment beyond 16 weeks.

Special Populations: *Elderly:* No dose adjustment required. *Renal or hepatic impairment:* No dose adjustment required. *Paediatric Population:* No data available.

CONTRAINDICATIONS: Hypersensitivity to any of the active substances or excipients. Clinically important active infections.

SPECIAL WARNINGS AND PRECAUTIONS: See SmPC for full details. Skyrizi may increase the risk of infections. In patients with a chronic infection or history of recurrent infections, 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. Patients should be evaluated for tuberculosis infection prior to initiating treatment. Anti-TB therapy should be considered prior to initiating Skyrizi in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Completion of all appropriate immunisations should be considered prior to initiating therapy. 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. Skyrizi contains 68.0 mg sorbitol and less than 1 mmol sodium (23 mg) per 150 mg dose.

INTERACTIONS: The safety and efficacy of Skyrizi in combination with immunosuppressants, including biologics or phototherapy have not been evaluated.

PREGNANCY AND LACTATION: Women of Childbearing potential: An effective method of contraception during treatment and for at least 21 weeks after treatment should be used. Pregnancy: Limited data available. It is preferable to avoid the use of Skyrizi during pregnancy as a precautionary measure. Lactation: It is not known whether Skyrizi is excreted in breast milk. Skyrizi may be used during breast-feeding if clinically needed.

Fertility: The effect of Skyrizi on human fertility has not been evaluated.

ADVERSE REACTIONS: See SmPC for full details on adverse reactions. **Very common adverse reactions** ($\geq 1/10$): Upper respiratory infections. **Common adverse reactions** ($\geq 1/100$ to $< 1/10$): Tinea infections, headache, pruritus, fatigue and injection site reactions.

LEGAL CLASSIFICATION: POM

MARKETING AUTHORISATION NUMBERS/PRESENTATIONS/NHS LIST PRICE:

EU/1/19/1361/001: Skyrizi 75 mg solution for injection in pre-filled syringe (Pack of 2 pre-filled syringes): £3326.09

LOCAL REPRESENTATIVE: AbbVie Ltd, Maidenhead, SL6 4UB

DATE OF REVISION: April 2019

PI-Skyrizi-001

Adverse events should be reported. Reporting forms and information can be found at: <https://yellowcard.mhra.gov.uk>. Adverse events should also be reported to AbbVie on GBPv@abbvie.com