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. *Overweight patients:* No dose adjustment required. **CONTRAINDICATIONS:** Hypersensitivity to any of the active substances or excipients. Clinically important active infections (e.g. active tuberculosis). **SPECIAL WARNINGS AND PRECAUTIONS**: See SmPC for full details. In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. 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. If a serious hypersensitivity reaction occurs, administration of Skyrizi should be discontinued immediately and appropriate therapy initiated. 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. Human IgGs are known to be excreted in breast milk during the first few days after birth, which decreases to low concentrations soon afterwards; consequently, a risk to the breast-fed infant cannot be excluded during this short period. A decision should be made whether to discontinue/abstain from Skyrizi therapy, taking into account the benefit of breast-feeding to the child and the benefit of Skyrizi therapy to the woman. **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 (≥1/10):*** Upper respiratory infections. ***Common adverse reactions (≥1/100 to <1/10):*** Tinea infections, headache, pruritus, fatigue and injection site reactions.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance; Website: www.hpra.ie. Suspected adverse events should also be reported to AbbVie Limited on 01-4287900.

LEGAL CLASSIFICATION: POM (S1A). **MARKETING AUTHORISATION NUMBERS/PRESENTATIONS**: EU/1/19/1361/001: Skyrizi 75 mg solution for injection in pre-filled syringe (Pack of 2 pre-filled syringes). **Further information is available from**: AbbVie Ltd., 14 Riverwalk, Citywest Business Campus, Dublin 24. **DATE OF REVISION**: March 2020. **PI/1361/002**

HRQoL, Health-Related Quality of Life; **PASI**, Psoriasis Area Severity Index.

REFERENCES: **1.** Gordon KB, et al. Lancet 2018; 392: 650-661. **2.** Ryan C *et al.* Poster presented at the 27th European Academy of Dermatology & Venerology (EADV) Congress 2018; September 12–16; Paris, France.

Skyrizi® Summary of Product Characteristics, available on www.medicines.ie.

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Skyrizi®▼
(risankizumab)

When it comes to your patients' **psoriasis treatment goals**

NOTHING IS EVERYTHING

What means everything to the patient? The potential for nothing left on their skin.*

* **Nothing on the skin**: Defined as 75% achievement of PASI90 at Week 16 and ≥50% achievement of PASI 100 at Week 52 in UltIMMa-1 and UltIMMa-2.[1]

High skin clearance matters to patients: Patients who achieve and maintain high levels of skin clearance (PASI 90-99 or PASI 100) have significantly better HRQoL than those with lower levels of skin clearance (PASI 75-89).[2]

Sustaining high skin clearance or complete skin clearance is associated with incremental and durable benefits in HRQoL and mental health of psoriasis patients.[2]