ABBREVIATED PRESCRIBING INFORMATION

SKYRIZI® (risankizumab) 150 mg solution for injection in pre-filled pen.

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

PRESENTATION: Each pre-filled pen contains 150 mg risankizumab in 1 mL solution.

INDICATIONS: Plaque Psoriasis: For treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. **Psoriatic Arthritis:** alone or in combination with methotrexate (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 disease-modifying antirheumatic drugs (DMARDs).

DOSAGE AND ADMINISTRATION: Intended for use under guidance and supervision of a physician experienced in diagnosis and treatment of conditions for which Skyrizi is indicated. **Dosage:** The recommended dose of Skyrizi is 150 mg 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 plaque psoriasis patients with initial partial response may subsequently improve with continued treatment beyond 16 weeks. **Special Populations:** *Elderly:* No dose adjustment required. Limited information aged ≥65 years. *Renal or hepatic impairment:* No dose adjustment considered necessary. *Paediatric Population:* No data; safety and efficacy not yet established. *Overweight patients:* No dose adjustment required. **Method of administration:** Subcutaneous injection in thigh or abdomen. Patients may self-inject after training. Administration in upper, outer arm only by HCP or caregiver.

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. Risankizumab may increase the risk of infections. In patients with a chronic infection, a history of recurrent infection, or known risk factors for infection, risankizumab should be used with caution. Treatment should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops such an infection or is not responding to standard therapy for the infection, the patient should be closely monitored and risankizumab should not be administered until the infection resolves. Patients should be evaluated for tuberculosis (TB) infection prior to initiating treatment. Monitor for signs and symptoms of active TB. Anti-TB therapy should be considered prior to initiating risankizumab 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 risankizumab. Patients treated with risankizumab should not receive live vaccines during treatment and for at least 21 weeks after treatment. If a serious hypersensitivity reaction, including anaphylaxis, occurs, administration of risankizumab should be discontinued immediately and appropriate therapy initiated. Excipients with known effect: contains less than 1 mmol sodium (23 mg) per pre-filled pen, that is to say essentially 'sodium free'.

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

FERTILITY, 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 risankizumab during pregnancy as a precautionary measure. Lactation: It is not known whether risankizumab is excreted in breast milk. A decision should be made whether to discontinue/abstain from risankizumab therapy, taking into account the benefit of breast-feeding to the child and the benefit of risankizumab therapy to the woman. Fertility: The effect of risankizumab on human fertility has not been evaluated.

UNDESIRABLE EFFECTS: ***Very common*** *(≥1/10):* Upper respiratory infections. ***Common*** *(≥1/100 to <1/10):* Tinea infections, headache, pruritus, rash, eczema, fatigue, injection site reactions. Refer to Section 4.8 of the SmPC for details of other side effects, and for further information.

Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance; website: www.hpra.ie.

LEGAL CLASSIFICATION: POM (S1A)

MARKETING AUTHORISATION HOLDER: AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061 Ludwigshafen, Germany.

MARKETING AUTHORISATION NUMBER: EU/1/19/1361/002

Further information is available on request from: AbbVie Limited, 14 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.
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