Prescribing Information: OTEZLA® (apremilast) 10mg, 20mg and 30mg film coated-tablets.

Refer to the Summary of Product Characteristics (SPC) before prescribing. Further information is available upon request

Presentation: 10mg, 20mg and 30mg film coated-tablets.

Indications: Psoriatic arthritis: OTEZLA®, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy. Psoriasis: OTEZLA® is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or psoralsen and ultraviolet-A light (PUVA).

Dosage and administration: Treatment with OTEZLA® should be initiated by specialists experienced in the diagnosis and treatment of psoriasis or psoriatic arthritis. The recommended dose of OTEZLA® is 30mg twice daily taken orally, morning and evening, approximately 12 hours apart, with no food restrictions. The film-coated tablets should be swallowed whole. To reduce risk of gastrointestinal symptoms, an initial dose titration is required per the following schedule: Day 1: 10mg in the AM; Day 2: 10mg in the AM and 10mg in the PM; Day 3: 10mg in the AM and 20mg in the PM; Day 4: 20mg in the AM and 20mg in the PM; Day 5: 20mg in the AM and 30mg in the evening; Day 6 and thereafter: 30mg twice daily. No titration is required after initial titration. If patients miss a dose, the next dose should be taken as soon as possible. If it is close to the time for their next dose, the missed dose should not be taken and the next dose should be taken at the regular time. During pivotal trials the greatest improvement was observed within the first 24 weeks of treatment. If a patient shows no evidence of therapeutic benefit after 24 weeks, treatment should be reconsidered. The patient’s response to treatment should be evaluated on a regular basis.

Special populations: Elderly patients: No dose adjustment is required for this patient population. Patients with renal impairment: No dose adjustment is needed in patients with mild and moderate renal impairment. The dose of OTEZLA® should be reduced to 30mg once daily in patients with severe renal impairment. OTEZLA® can be co-administered with methotrexate. There was no pharmacodynamic drug-drug interaction between OTEZLA® and oral contraceptives containing ethinyl estradiol and norgestimate. OTEZLA® can be co-administered with oral contraceptives.

Side effects: The most commonly reported adverse reactions in Phase III clinical studies have been gastrointestinal disorders including diarrhea and nausea. The other most commonly reported adverse reactions included upper respiratory tract infections, headache, and tense headache. The most common adverse reactions leading to discontinuation during the first 16 weeks of treatment were diarrhea, and nausea. The overall incidence of serious adverse reactions was low and did not indicate any specific system organ involvement. Very commonly reported adverse events are listed as: diarrhea*, and nausea*. Common adverse events are listed as: bronchitis, upper respiratory tract infection, nasopharyngitis*, decreased appetite*, insomnia, depression, migraine*, tension headache*, headache*, cough, vomiting*, dyspepsia, frequent bowel movements, upper abdominal pain*, gastroesophageal reflux disease, back pain*, fatigue. Prescribers should consult the summary of product characteristics in relation to other side-effects. Hypersensitivity* and risk of triggering suicide* have also been reported. * At least one of these was reported as serious or could be considered serious.

Legal category: POM Marketing authorisation numbers: EU/1/14/981/001, EU/1/14/981/002 and EU/1/14/981/003. Marketing authorisation holder: Celgene Europe BV, Winhtontlaan 6 N, 3526KV Utrecht, Netherlands. For further information contact: Celgene Ltd, 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB, United Kingdom Tel: +44(0)208 831 8300.

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Please report any suspected adverse reactions directly to the Health Products Regulatory Authority (HPRA) using the online forms at www.hpra.ie or the freephone reporting system. 

Adverse events should also be reported to Celgene Drug Safety Tel: 1800 936 217 Fax: 1800 936 477