PRESCRIBING INFORMATION

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

▼ Ilumetri 100 mg solution for injection in pre-filled syringe.

Active Ingredient:
Each pre-filled syringe contains 100 mg of tildrakizumab in 1 ml. Tildrakizumab is a humanised IgG1/k monoclonal antibody produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology.

Indication: Ilumetri is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy.

Dosage and Administration:. The recommended dose of Ilumetri is 100 mg by subcutaneous injection at weeks 0, and 4 and every 12 weeks thereafter. In patients with certain characteristics (e.g. high disease burden, body weight ≥ 90 kg) 200 mg may provide greater efficacy. Consideration should be given to discontinuing treatment in patients who have shown no response after 28 weeks of treatment. Some patients with initial partial response may subsequently improve with continued treatment beyond 28 weeks. Injection sites should be alternated. *Elderly:* No dose adjustment is required. *Paediatric population*: No data available. *Renal or hepatic Impairment*: No dosage recommendations can be made. *Consult SmPC and package leaflet for full method of administration.*

Contraindications, Warnings, etc:
Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in SmPC section 6.1. Clinically important active infection, e.g. active tuberculosis.
Precautions: In order to improve traceability always record the batch number of the administered product. Ilumetri may have the potential to increase the risk of infections. If a patient develops a serious infection, the patient should be closely monitored and treatment with Ilumetri should not be administered until the infection resolves. Exercise caution in patients with a chronic infection or a history of recurrent or recent serious infection. Instruct patients to seek medical advice if signs or symptoms of an infection occur. Patients should be evaluated for tuberculosis (TB) prior to initiation of treatment and monitored for signs and symptoms of active TB during and after treatment. In patients with a past history of latent or active TB, consideration for Anti-TB therapy should be given. Discontinue use if a serious hypersensitivity occurs. All appropriate immunisations should be completed prior to start of treatment with Ilumetri. Patients treated with Ilumetri should not receive live vaccine during treatment and for at least 17 weeks after treatment. *Consult SmPC and package leaflet for more information. Fertility, pregnancy and lactation:* Women of childbearing potential should use effective methods of contraception during treatment and for 17 weeks after treatment. As a precautionary measure, it is preferable to avoid the use of Ilumetri during pregnancy. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Ilumetri therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. The effect of Ilumetri on human fertility has not been evaluated. *Consult SmPC and package leaflet for more information.*

Adverse Reactions: *Very common (≥1/10);*Upper respiratory tract infections, including nasopharyngitis.
Common (≥1/100 to <1/10): Headache, gastroenteritis, nausea, diarrhoea, injection site pain, back pain *Consult SmPC and package leaflet for other adverse reactions.*

Legal Category: POM

Marketing Authorisation Number(s): EU/1/18/1323/001
EU/1/18/1323/002

NHS Cost: (excluding VAT).
1 x 100 mg solution in a prefilled syringe - £3,241
2 x 100 mg solution in a prefilled syringe - £3,241

Marketing Authorisation Holder: Almirall, S.A., Ronda General Mitre, 151, 08022 Barcelona, Spain.

Further information is available from:
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Almirall Ltd.