ILUMETRI® (tildrakizumab) PRESCRIBING INFORMATION

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

ILUMETRI® is available as 100 mg and 200 mg solution for injection in pre-filled syringes and as 100 mg solution for injection in pre-filled pen (autoinjector).

Active Ingredient: Each pre-filled syringe contains 100 mg or 200 mg of tildrakizumab in 1 mL or 2 mL. Each pre-filled pen contains 100 mg of tildrakizumab in 1mL. 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, 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. *Renal or hepatic impairment*: No dosage recommendations can be made. *Paediatric population*: No data available.

Contraindications, Precautions and Warnings:
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: To improve traceability always record the batch number of the administered product. ILUMETRI has 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 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. If a patient has received live viral or bacterial vaccination it is recommended to wait at least 4 weeks prior to starting treatment with ILUMETRI. Patients treated with ILUMETRI should not receive live vaccine during treatment and for at least 17 weeks after treatment.
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.

Adverse Reactions: *Very common (≥1/10):* Upper respiratory tract infections. *Common (≥1/100 to <1/10):* Headache, gastroenteritis, nausea, diarrhoea, injection site pain, back pain. Immunogenicity: In pooled Phase 2b and Phase 3 analyses, 7.3% of tildrakizumab-treated patients developed antibodies to tildrakizumab up to week 64. Of the subjects who developed antibodies to tildrakizumab, 38% (22/57 patients) had neutralizing antibodies. This represents 2.8% of all subjects receiving tildrakizumab.

Please consult Summary of Product Characteristics for further information.

Legal Category:
Ireland: Subject to prescription which may not be renewed (A).
United Kingdom & UK/NI: POM

Price & Pack:
United Kingdom
100 mg pre-filled syringe - £3,241
200 mg pre-filled pen - £3,241
100 mg pre-filled pen - £3,241
Ireland
100 mg pre-filled syringe - € 3,075.60
200 mg pre-filled pen - € 3,075.60
100 mg pre-filled pen - € 3,075.60

Marketing Authorisation Number(s):
IE & UK(NI) - EU/1/18/1323/001 ; EU/1/18/1323/003 ; EU/1/18/1323/004
GB - PLGB 16973/0038 ; PLGB 16973/0045 ; PLGB 16973/0047

Further information available from:
Almirall Limited, Harman House, 1 George Street, Uxbridge, Middlesex, UB8 1QQ, UK.

Date of Revision: 02/2024

Item code: IE-ILU-2400008

UK-Adverse events should be reported.
Reporting forms and information can be found at MHRA https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should be also reported to Almirall Ltd. Tel. 0800 0087 399

IE-Adverse events should be reported.
Reporting forms and information can be found at HPRA Pharmacovigilance, Website: www.hpra.ie.
Adverse events should be also reported to Almirall Ltd. Email: Almirall@EU.ProPharmaGroup.com