POTELIGEO® (mogamulizumab) 4 mg/mL concentrate for solution for infusion

Prescribing Information - EU

For full prescribing information please refer to the Summary of Product Characteristics (SmPC)

Active ingredient: Mogamulizumab (4 mg/mL).

Presentation: Concentrate for solution for infusion. Available as 20 mg mogamulizumab in 5 mL solution (4 mg/mL) in a 10 mL glass vial.

Indication: Treatment of adult patients with mycosis fungoides (MF) or Sézary syndrome (SS) who have received at least one prior systemic therapy.

Dosage and administration: The recommended dose is 1 mg/kg POTELIGEO administered as an intravenous infusion only, over at least 60 minutes. Treatment must be initiated and supervised by physicians experienced in the treatment of cancer and should only be administered in an environment where resuscitation equipment is available. Administration is weekly on days 1, 8, 15 and 22 of the first 28-day cycle, followed by infusions every two weeks on Days 1 and 15 of each subsequent 28-day cycle until disease progression or unacceptable toxicity. Pre-medication with antipyretic and antihistamine is recommended for the first infusion. If an infusion reaction occurs, administer pre-medication for subsequent infusions. Patients receiving POTELIGEO have experienced drug rash (drug eruption), some of which were severe and/or serious. In the event of moderate or severe (Grade 2–3) drug-related rash, treatment with POTELIGEO must be interrupted and the rash treated appropriately until it improves to mild severity (Grade 1) or less, at which time treatment may be resumed; POTELIGEO should be permanently discontinued in the event of a life-threatening (Grade 4) rash. Acute infusion-related reactions (IRRs) have been observed in patients treated with POTELIGEO. The IRRs were mostly mild or moderate in severity (Grade 1–2), although there have been a few reports of severe reactions (Grade 3). The majority of IRRs occur during or shortly after the first infusion (all within 24 hours of administration), with the incidence decreasing over subsequent treatments. For mild to severe (Grade 1–3) IRRs, POTELIGEO treatment should be temporarily interrupted and symptoms treated. The infusion rate should be reduced by at least 50% when restarting the infusion after symptoms resolve. If reaction recurs, discontinuing the infusion should be considered. POTELIGEO treatment should be permanently discontinued for a life-threatening (Grade 4) IRR.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Special warnings and precautions: When POTELIGEO has been administered to patients with T-cell lymphomas other than MF or SS, serious skin reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), have been reported in less than 1% of patients during clinical trials, and also during the post-marketing period; some of these cases were reported with fatal outcomes. Patients should be closely monitored for symptoms or signs that suggest SJS or TEN. If they occur, treatment with POTELIGEO should be interrupted and should not restart unless SJS or TEN is ruled out and cutaneous reaction has resolved to Grade 1 or less. Subjects with MF or SS treated with POTELIGEO are at increased risk of serious infection and/or viral reactivation. Combining POTELIGEO with systemic immunomodulatory agents or with other licensed therapies for MF or SS has not been studied and is, therefore, not recommended. Topical steroids or low doses of systemic corticosteroids may be used during treatment with POTELIGEO however, the risk of serious infection and/or viral reactivation may be higher. Patients should be monitored for signs and symptoms of infection and treated promptly. Patients should be tested for hepatitis B infection before initiating treatment with POTELIGEO; for patients positive for current/previous infection, consultation with a physician with expertise in the treatment of hepatitis B is recommended. Complications, including severe graft versus host disease (GvHD), have been reported in patients who received allogeneic haematopoietic stem cell transplantation (allo-HSCT) after POTELIGEO. A higher risk of transplant complications has been reported if POTELIGEO is given within a short time frame (~ 50 days) before HSCT. Follow patients closely for early evidence of transplant-related complications. Tumour lysis syndrome (TLS) has been observed in patients receiving POTELIGEO. Patients should be monitored closely by appropriate laboratory and clinical tests for electrolyte status, hydration and renal function, particularly in the first month of treatment, and managed according to best medical practice. Patients who have risk factors associated with cardiac disease should be monitored and appropriate precautions taken.

Undesirable effects: The most frequently reported serious adverse reactions were pneumonia, pyrexia, infusion related reaction and cellulitis. Severe adverse reactions included Grade 4 respiratory failure (1.1%) and Grade 5 reactions were polymyositis and sepsis (0.5% each). Very common (≥1/10) adverse reactions included; constipation, diarrhoea, nausea, stomatitis, fatigue, oedema peripheral, pyrexia, infections, infusion-related reaction, headache, drug eruption (including skin rash). Common (≥1/100 to <1/10) adverse reactions included; anaemia, neutropenia, leukopenia, thrombocytopenia, hypothyroidism, vomiting, upper respiratory tract infection, elevated liver enzymes, lymphocyte count decreased. Please consult the SmPC in relation to other undesirable effects.

Legal category: PoM

Price: 1 x 20 mg vial = £1,329.00

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POTELIGEO® is a registered trademark

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Adverse Events should be reported.
Reporting forms and information can be found at https://yellowcard.mhra.gov.uk. Adverse events should also be reported to Kyowa Kirin Ltd on +44 (0)1896 664000, email medinfo@kyowakirin.com