LEMTRADA (alemtuzumab) 12 mg concentrate for solution for infusion. Please refer to the Summary of Product Characteristics (SPC) before prescribing. PRODUCT COMPOSITION: Monoclonal antibody produced in mammalian cells (Chinese Hamster Ovary). INDICATION: LEMTRADA is indicated as a single disease modifying therapy in adults with highly active relapsing remitting multiple sclerosis (RRMS) for the following patient groups :Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy (DMT) or Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI. DOSAGE AND ADMINISTRATION: Treatment should only be initiated and supervised by a neurologist experienced in the treatment of patients with MS in a hospital with ready access to intensive care Specialists and equipment required for the timely diagnosis and management of adverse reactions, especially myocardial ischaemia and myocardial infarction, cerebrovascular adverse reactions, autoimmune conditions, and infections, should be available. Recommended dose: 12 mg/day i.v. for 2 treatment courses. with up to 2 additional treatment courses if needed. Initial treatment course: 12 mg/day for 5 consecutive days (60 mg total dose). Second treatment course (after 12 months): 12 mg/day for 3 consecutive days (36 mg total dose). Third or fourth course: 12 mg/day on 3 consecutive days (36 mg total dose) administered at least 12 months after the prior treatment course Follow-up of patients. The therapy is recommended as an initial treatment of 2 courses with up to 2 additional treatment courses if needed with safety follow-up of patients from initiation of the first treatment course and for at least 48 months after the last infusion of the second treatment course. If an additional third or fourth course is administered, continue safety follow-up for at least 48 months after the last infusion. PRE-TREATMENT: Corticosteroids immediately prior to LEMTRADA administration on each of the first 3 days of any treatment course. Additionally, anti-histamines and/or antipyretics may be considered. Prophylaxis with an oral anti-herpes agent (e.g. aciclovir) on the first day of treatment, continue for a minimum of 1 month following each treatment course. EDUCATIONAL GUIDANCE: Physicians must familiarise themselves with educational materials: Healthcare Professional Guide, Prescriber Checklist, and provide their patients with a Patient Guide, Patient Alert Card and Package Leaflet. Patients must be informed about the risks and benefits, and the need to commit to 4 years of follow-up after the last infusion. WARNINGS AND PRECAUTIONS: Risk of autoimmune mediated conditions including immune thrombocytopenic purpura (ITP), thyroid disorders, nephropathies including anti-Glomerular Basement Membrane (anti-GBM) disease, and other autoimmune cytopenias. Monthly or quarterly monitoring as detailed in the SPC is required for 4 years after the last infusion in order to detect abnormalities and initiate treatment and/or immediate referral to a specialist. After this period of time testing should be performed based on clinical findings. ITP: Obtain complete blood count (CBC) with differential prior to initiation of treatment and at monthly intervals. Nephropathies: Obtain serum creatinine levels and urinalysis with microscopy prior to initiation of treatment and at monthly intervals. Thyroid disorders: Obtain thyroid function tests, such as thyroid stimulating hormone levels, prior to initiation of treatment and every 3 months. Cytopenia: CBC results should be used to monitor for autoimmune cytopenias such as neutropenia, haemolytic anaemia and pancytopenia. Infusion-Associated Reactions (IARs): Mild to moderate IARs in most patients during and/or up to 24 hours. Check patients cardiac history as IARs can include cardiac symptoms such as tachycardia. Resources for the management of anaphylaxis or serious reactions should be available. Serious Infections: Consider delaying initiation of treatment in patients with active infection until fully controlled. Screen patients at high risk of Hepatitis B or C Virus infection. Female patients: Complete annually cervical Human

Papilloma Virus screening. Before initiation of treatment, all patients must be evaluated for active or inactive ("latent") tuberculosis infection. Concomitant use: Potential combined effects on the patient's immune system if administered with other immunomodulating therapies. Malignancy: Caution in initiating treatment in patients with pre-existing and/or an on-going malignancy. Vaccination: Complete local immunisation requirements at least 6 weeks prior to treatment. Live viral vaccines should not be administered following a course of LEMTRADA. Varicella zoster virus vaccination of antibody-negative patients should be considered at least 6 weeks prior to treatment initiation. UNDESIRABLE EFFECTS: Very common (≥ 1/10) Upper respiratory tract infection, urinary tract infection, lymphopenia, leukopenia, headache, flushing, nausea, urticaria, rash, pruritus, pyrexia, fatigue. Common (≥ 1/100 to < 1/10): Lower respiratory tract infections, herpes zoster, gastroenteritis, oral herpes, oral candidiasis, vulvovaginal candidiasis, influenza, ear infection, lymphadenopathy, cytokine release syndrome, Basedow's disease, hyperthyroidism, autoimmune thyroiditis, hypothyroidism, goitre , anti-thyroid antibody positive, insomnia, anxiety, MS relapse, dizziness, hypoaesthesia, paraesthesia, tremor, dysgeusia, blurred vision, vertigo, tachycardia, bradycardia, palpitations, hypotension, hypertension, dyspnoea, cough, epistaxis, oropharyngeal pain, abdominal pain, vomiting, diarrhoea dyspepsia, stomatitis, generalised rash, erythema, ecchymosis, alopecia, hyperhidrosis, acne, myalgia, muscle weakness, arthralgia, back pain, pain in extremity, muscle spasms, neck pain, proteinuria, haematuria, menorrhagia, irregular menstruation, chest discomfort, chills, pain, oedema peripheral, asthenia, influenza-like illness, malaise, infusion site pain, contusion. Uncommon (≥ 1/1,000 to < 1/100) effects of interest: (selected) ITP, thrombocytopenia, haemoglobin decreased, haematocrit decreased, depression, aspartate aminotransferase increased. CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients. Human Immunodeficiency Virus (HIV) infection. PREGNANCY AND LACTATION: Women of child bearing potential should use effective contraceptive measures during and for 4 months following each treatment course. Administer LEMTRADA during pregnancy only if the potential benefit justifies the potential risk to the foetus. Thyroid disease poses special risks in women who are pregnant. Untreated hypothyroidism in pregnancy is associated with an increased risk of miscarriage and foetal effects. Discontinue breast feeding during each course and for 4 months following each treatment course. MARKETING AUTHORISATION HOLDER: Sanofi Belgium Leonardo Da Vincilaan 19 B-1831 Diegem Belgium., August 2021. Full SMPC available upon request