Levothyroxine SERB 200 micrograms/ml solution for injection/infusion. Please consult Summary of Product Characteristics (SmPC) before prescribing.

Presentation & composition: Levothyroxine sodium 200 micrograms for one ampoule of 1ml solution for injection/infusion. Clear colourless solution.

Indication: Myxoedema coma. Hypothyroidism in patients where oral therapy is not feasible, particularly due to difficulties in swallowing or malabsorption.

Dosage: Perform thyroid function test (T3, T4 and TSH levels) before treatment with levothyroxine injection. The starting and maintenance doses depend on the degree of hypothyroidism, the patient's age and individual tolerance. Daily administration of levothyroxine injection should be continued until the patient is able to tolerate oral therapy. *Adults- Myxoedema coma:* An initial loading dose of 200 to 500 micrograms on the first day is recommended. Due to an increased risk of serious cardiovascular events or death, this loading dose must not exceed 500 micrograms. The maintenance dose of parenteral levothyroxine is 1.2 micrograms per kilogram body weight (75-90 micrograms). *Hypothyroidism where oral therapy is not feasible:* Oral to iv conversion: Gastrointestinal absorption of oral levothyroxine tablet is approximately 70%–80% in healthy fasting adults, therefore, parenteral levothyroxine should be administered at an initial dose that corresponds to 70-80% of the patient's oral dose. Complete hormone replacement therapy in adults requires 100 to 150 micrograms as a single daily dose, on average. This dosage will be established gradually and with caution: start with 25 micrograms per day, then increase the daily dose by 25 micrograms at weekly intervals. Once the dosage has been stable for a long enough period (4-6 weeks), repeat testing of thyroid hormones levels. Monitor T3 and T4 levels to check that there is no overdose and monitor normalisation of TSH levels in the event of peripheral hypothyroidism. *Elderly patients:* More gradual dosing schedules may be proposed, particularly in elderly subjects with known cardiovascular risk factors, for whom treatment should be initiated at lower doses, and follow more gradual increments. A maintenance dose lower than that required to normalise TSH levels may be considered. *Patients with renal / hepatic insufficiency:* Experience in patients with renal and/or hepatic insufficiency is limited. *Paediatric population- Myxoedema coma:* Experience in children treated for myxoedema coma is very limited. Use of parenteral levothyroxine 10 micrograms/kg/day in 3 divided doses for 24 hours as loading dose followed by 3 micrograms/kg/day as maintenance therapy has been reported in published case reports. Dose should be adjusted based on clinical and laboratory findings. *Hypothyroidism where oral therapy is not feasible:* The daily replacement dose of intravenous levothyroxine should be no more than 75% of the oral dose. In all cases, the dose should be adjusted based on the needs of each individual.

Administration: Intravenous injection. Intramuscular injection possible. For the treatment of myxoedema coma, an initial loading dose is given as a slow intravenous infusion in 100-250 ml of sodium chloride 9 mg/mL (0.9%) solution for injection solution to achieve a concentration of the diluted solution of 2 micrograms/ml.

Contraindications: Hypersensitivity to the active substance or to any of the excipients (Sodium hydroxide, water for injections). Decompensated cardiac diseases (e.g. acute myocardial infarction, acute myocarditis, acute pancarditis). Untreated adrenal insufficiency. Untreated hyperthyroidism. Untreated pituitary insufficiency (when leading to adrenal insufficiency requiring treatment). Combination of levothyroxine with an antithyroid agent for hyperthyroidism is not indicated during pregnancy.

Warnings & Precautions: Before starting a thyroid hormone therapy, the following diseases or conditions should be excluded or treated: Coronary heart disease, angina pectoris, hypertension, pituitary and/or adrenal insufficiency, thyroid autonomy. It is essential that even mild, drug-induced hyperthyroidism be avoided in patients with coronary heart disease, heart failure, tachyarrhythmias, myocarditis of non-acute course, chronic hypothyroidism or in patients who have already suffered a myocardial infarction. In these patients, more frequent monitoring of thyroid hormone parameters is essential during thyroid hormone therapy. Thyroid hormones should not be given for weight reduction. In euthyroid patients, treatment with levothyroxine does not cause weight reduction. Substantial doses may cause serious or even life-threatening undesirable effects, particularly in combination with certain substances for weight reduction, and especially with sympathomimetic amines. If a switch to another levothyroxine-containing product is required, there is a need to undertake a close monitoring including clinical and laboratory monitoring during the transition period due to a potential risk of thyroid imbalance. In some patients, dose adjustment may be necessary. Due to the difference in bioavailability of the oral dosage form versus injectable form, the dose should be carefully adapted when switching from one form to another. *Patients with cardiovascular disorders or with a history of cardiovascular disorders:* Levothyroxine by the intravenous/intramuscular route can be associated with cardiac toxicity in patients with underlying cardiovascular disease. Due to the increased prevalence of cardiovascular diseases in the elderly, caution is required when administering levothyroxine in elderly patients or those with known cardiac risk factors. Cautious use may be required in these populations, including at doses at the lower end of the recommended dosage range. Regular and careful monitoring of cardiac conditions is necessary at treatment initiation and throughout treatment. *Patients with adrenal insufficiency*: In case adrenocortical dysfunction occurs concomitantly with myxoedema coma, patients should be treated with glucocorticoids before starting levothyroxine. *Low birth weight preterm neonates:* Haemodynamic parameters should be monitored when levothyroxine therapy is initiated in very low birth weight preterm neonates as circulatory collapse may occur due to the immature adrenal function. The proposed dose of Levothyroxine SERB may be a significant addition to the circulating blood volume of preterm infants. This should be taken into account when calculating daily fluid requirements. This should be considered when calculating daily fluid requirements. *Diabetes:* The addition of levothyroxine to an anti-diabetic treatment or insulin therapy can lead to an increase in insulin or anti-diabetic drug requirements. Careful monitoring of metabolic control is recommended in diabetic patients. *Patients with a history of epilepsy*: Due to the risk of seizures in patients with a history of epilepsy, monitoring of these patients is recommended throughout treatment with levothyroxine. *Hypersensitivity:* Hypersensitivity reactions (including angioedema), sometimes serious, have been reported. If signs and symptoms of allergic reactions occur, treatment with Levothyroxine SERB, 200 micrograms/ml solution for injection/infusion must be discontinued and appropriate symptomatic treatment initiated. *Osteoporosis:* During levothyroxine therapy of postmenopausal women with increased risk of osteoporosis, dosage of levothyroxine sodium should be titrated to the lowest possible effective level and thyroid function should be monitored more frequently to avoid levels of levothyroxine above the physiological range.

Interactions: Combinations not recommended - St. John's Wort (Hypericum perforatum). Combinations requiring precautions for use - Anti-diabetic agents, coumarin derivatives, propylthiouracil, glucocorticoids and beta-receptor blockers (especially propranolol), amiodarone and contrast media containing iodine, salicylate, dicumarol, furosemide, clofibrate, contraceptives containing oestrogen, drugs for post-menopausal hormone substitution, androgens, sertraline, chloroquine/proguanil, enzyme inducing drugs, protease inhibitors, tyrosine kinase inhibitors (e.g. Imatinib, sunitinib, sorafenib, motesanib, selpercatinib).

Fertility, Pregnancy and lactation: Pregnancy - Data concerning the use of levothyroxine injections in pregnant women are limited. It is essential that thyroid hormone treatment be continued throughout pregnancy to maintain the balance required in the mother to ensure a healthy pregnancy (and, in particular, to reduce the risk of foetal hypothyroidism). Clinical and laboratory monitoring must be performed as soon as possible, particularly during the first half of the pregnancy, so that the treatment can be adjusted if necessary. In all cases, it is recommended that a thyroid assessment be performed on the newborn infant. In breast-feeding women with balanced T4 levels,

levothyroxine is secreted into breast milk in low concentrations. Consequently, replacement therapy using levothyroxine is possible while breast-feeding. No fertility studies have been performed. Please consult the SmPC for full information. During pregnancy, levothyroxine must not be combined with anti-thyroid agents for hyperthyroidism.

Driving and machines: Levothyroxine SERB 200 micrograms/ml solution for injection/infusion has no effect or a negligible effect on the ability to drive and use machines.

Undesirable effects:
Very common: Insomnia, headache, palpitations. Common: Hyperthyroidism, nervousness, tachycardia. *Rare*: Pseudotumor cerebri particularly in children. *Not known*: Hypersensitivity, agitation, tremors, cardiac arrhythmias, anginal pain, flushing, circulatory collapse in low birth weight preterm neonates, diarrhoea, vomiting and nausea, angioedema, rash, urticaria, sweating, muscle weakness and cramps, osteoporosis at suppressive doses of levothyroxine, especially in postmenopausal women, mainly when treated for a long period, menstrual irregularities, heat intolerance, fever, weight loss. Please consult the SmPC in relation to other adverse reactions**.**

List of excipients: Sodium hydroxide and Water for injections

Incompatibilities: In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf life: 2 years. After opening and/or dilution: the product must be used immediately.

Special precautions for storage: Store in the original container protected from light.

Nature and content of container: 1 ml ampoule (glass). Box of 6.

Special precautions for disposal and other handling: Do not use Levothyroxine SERB 200 micrograms/ml solution for injection/infusion if there is any visible particulate matter or discolouration. Any unused medicinal product or waste material should be disposed of in accordance with local requirements

Legal classification: POM

NHS Price: £650.00

UK Marketing Authorisation number: PL 26080/0010

Marketing authorisation holder: SERB SAS, 32 Rue de Monceau, 75008 Paris, France

Date of Preparation: July 2026

Job code: UK-LT/LTH-2300017

Date of first authorisation: 19 December 2022

Adverse reactions should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store

Adverse reactions should also be reported to Serb SAS via email at Safety@serb.com