PRESCRIBING INFORMATION Liothyronine Sodium 20 micrograms Tablets (liothyronine sodium)

Presentation: Each tablet contains 20mcg Liothyronine sodium BP.

Indication: Treatment of coma of myxoedema, severe chronic thyroid deficiency and hypothyroid states occurring in the treatment of thyrotoxicosis. It can also be used in the treatment of thyrotoxicosis as an adjunct to carbimazole to prevent sub-clinical hypothyroidism developing during treatment. Liothyronine sodium may be preferred for treating severe and acute hypothyroid states because of its rapid and more potent effect.

Dosage and Administration: *Adults:* Starting dose of 10 or 20 micrograms every 8 hours, increasing after one week, if necessary, to the usual recommended daily dose of 60 micrograms in two or three divided doses. *Myxoedema Coma:* 60 micrograms given by stomach tube, then 20 micrograms every 8 hours. *Adjunct to carbimazole treatment of thyrotoxicosis:* 20 micrograms every 8 hours. *Elderly and Children:* 5 micrograms daily (tablets can be crushed

and triturated with lactose for administration as a powder). **Contraindications:** Patients with angina of effort, cardiovascular diseases, thyrotoxicosis or hypersensitivity to any components of the tablet.

Precautions and warnings: Caution in patients with severe and prolonged hypothyroidism, diabetes mellitus, diabetes insipidus and patients with myxedema by avoiding excessive imposition of burden on cardiac muscle affected by prolonged severe thyroid depletion. Pan hypopituitarism or predisposition to adrenal insufficiency. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medication.

Interactions: Anticoagulants, cardiac glycosides, colestyramine, colestipol, antidiabetic agents, catecholamine's, oral contraceptives, anticonvulsants like carbamazepine and phenytoin, amiodarone, amitriptyline and oestrogens may affect thyroid function tests and this should be borne in mind when monitoring patients on Liothyronine therapy.

Pregnancy and lactation: Safety of the drug during pregnancy is not known. The risk of foetal congenital abnormalities should be weighed against the risk to the foetus of untreated maternal hypothyroidism. Liothyronine is excreted into breast milk in low concentrations which may interfere with neonatal screening programmes.

Undesirable effects: Anginal pain, cardiac arrhythmias, palpitations, muscle cramps, tachycardia, diarrhoea, restlessness, excitability, headache, flushing, sweating, excessive loss of weight and muscular weakness, vomiting, tremor, insomnia, fever, heat intolerance, transient hair loss in children, hypersensitivity reactions including rash, pruritus and oedema may occur and will disappear on reduction of dosage or withdrawal of treatment for a day or two.

(Please refer Summary of Product Characteristics for detailed information)

Overdose: Signs and symptoms may include agitation, confusion, irritability, hyperactivity, headache, sweating, mydriasis, tachycardia, arrhythmias, tachypnoea, pyrexia, increased bowel movements and convulsions.

Treatment of overdose is symptomatic but gastric lavage or emesis can be performed if patient is seen within a few hours of overdose.

Legal category: POM

Basic NHS cost: £ 258.20 per pack of 28 tablets

Marketing Authorisation Number: PL 10972/0033

Marketing Authorisation Holder: Amdipharm Mercury Company Limited (AMCo), 1st Floor, Capital House, 85 King William Street, London, EC4N 7BL.

Date of preparation: August 2012

Date of Revision: February 2016

Adverse events should be reported to the local regulatory authority. Reporting forms and information can be found at <u>www.mhra.gov.uk/yellowcard</u>. Adverse events should also be reported to **Amdipharm Mercury Medical Information** via telephone on **08700 70 30 33** or via e-mail at <u>medicalinformation@amcolimited.com</u>.