PRESCRIBING INFORMATION
Levothyroxine 25mcg, 50mcg and 100mcg tablets

Presentation: Each tablet contains 25, 50 or 100 micrograms of levothyroxine sodium anhydrous. **Indication:** Control of hypothyroidism, congenital hypothyroidism in infants, acquired hypothyroidism in children and juvenile myxoedema. **Dosage and Administration:** *Adults:* Initially 50-100mcg daily, preferably taken before breakfast or the first meal of the day. Adjust at 3-4 week intervals by 50mcg until normal metabolism is steadily maintained. *Patients aged over 50 years:* Initially, it is not advisable to exceed 50mcg daily. The daily dose may be increased by 50mcg at intervals of every 3-4 weeks, until stable thyroxine levels are attained. *Patients over 50 years with cardiac disease:* 25mcg daily or 50 mcg on alternate days is more suitable. *Paediatric patients:* The dose for neonates, infants and children depends on their age, weight and the condition being treated. **Contraindications:** Thyrotoxicosis, hypersensitivity to levothyroxine sodium or any components. Adrenal gland disorder or adrenal insufficiency. **Precautions and warnings:** Levothyroxine should be introduced very gradually in patients aged over 50 years and those with long standing hypothyroidism to avoid any sudden increase in metabolic demands. Patients with panhypopituitarism or other causes predisposing to adrenal insufficiency may react to levothyroxine treatment, and it is advisable to start corticosteroid therapy before giving levothyroxine to such patients. Levothyroxine sodium should be used with caution in patients with cardiovascular disorders, including angina, coronary artery disease, hypertension, and in the elderly. An ECG before starting treatment with levothyroxine is advised. Care is needed for patients with diabetes mellitus and diabetes insipidus. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. To minimise the risk of osteoporosis, dosage of levothyroxine sodium should be titrated to the lowest possible effective level. Parents of children receiving thyroid agent should be advised that partial loss of hair may occur during the first few months of therapy, but this effect is usually transient and subsequent regrowth usually occurs. **Interactions:** Anticoagulants (warfarin), anti-diabetic agents, tricyclic anti-depressants (e.g. amitriptyline, imipramine, dosulepin), sympathomimetic agents (e.g. adrenaline or phenylephrine), digoxin in digitalised patients, phenylbutazone, acetylsalicylic acid, beta blockers (propranolol, atenolol and sotalol), ketamine. Amiodarone, anti-convulsants (carbamazepine and phenytoin), sertraline, antacids, proton pump inhibitors, calcium salts, cimetidine, oral iron, sucralfate, colestipol, polystyrene sulphonate resin and cholestyramine, rifampicin, barbiturates, and primidone. Imatinib, androgens, corticosteroids, oestrogen and oral contraceptives. **Pregnancy and lactation:** The safety of levothyroxine treatment during pregnancy is not known, but any possible risk of foetal abnormalities should be weighed against the risk to the foetus of untreated hypothyroidism. Levothyroxine is excreted in breast milk in low concentrations, and it is contentious whether this can interfere with neonatal screening. **Undesirable effects:** Headache, flushing, fever and sweating. Hypersensitivity reactions including rash, pruritus, dyspnoea, joint pain, malaise and oedema. Weight loss, tremor, restlessness, excitability, insomnia. Cardiac disorders (anginal pain, cardiac arrhythmias, palpitations, tachycardia). Menstrual irregularities, diarrhoea, vomiting, muscle cramps, muscle weakness, craniostenosis in infants and premature closure of epiphysis in children. Heat intolerance, transient hair loss in children. Thyroid crisis (symptoms include hyperpyrexia, tachycardia, arrhythmia, hypotension, cardiac failure, jaundice, confusion, seizure and coma). ***(Please refer to the Summary of Product Characteristics for detailed information)***. **Overdose:** Give oral activated charcoal if more than 10mg has been ingested by an adult or more than 5mg by a child, within 1 hour. Take blood 6-12 hours after ingestion for measurement of the free thyroxine concentration and review 3-6 days after ingestion to detect delayed onset hyperthyroidism. Features of clinical hyperthyroidism should be controlled with beta-blockers, e.g. propranolol.
Legal category: POM
Basic NHS cost and pack size: Levothyroxine 25mcg x 28 tablets =£2.69; Levothyroxine 50mcg x 28 tablets =£1.84, Levothyroxine 100mcg x 28 tablets =£1.85
Marketing Authorisation Number: 25mcg: PL 12762/0016, 50mcg: PL 10972/0031, 100mcg: PL 10972/0032
Marketing Authorisation Holder: Amdipharm Mercury Company Limited (AMCo), 1st Floor,

Capital House, 85 King William Street, London, EC4N 7BL
Date of preparation: February 2016

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