SPMC

LEVOTHYROXINE TABLETS IP 50 mcg

PRESENTATION:

Levothyroxine Tablets IP 50 mcg:

Packs of 100 tablets & Blisters containing 10 Tablets. (10x10) White colored 6.5 mm circular tablets. Each Tablet contains 50 mcg Levothyroxine sodium.

MECHANISM OF ACTION:

Levothyroxine sodium used for the treatment of hypothyroidism. The Thyroid gland is dependent upon 2 active principles for its main hormone activity. These are Levothyroxine (Tetraiodothyronine) and Tri-iodothyronine (see Goodman and Gilman, 1985). These closely related iodine containing amino acids are incorporated into the glycoprotein thyroglobulin. Levothyroxine is deiodinated in peripheral tissues to form triiodothyronine which is thought to be the active tissue form of thyroid hormone. Triiodothyronine has a rapid action but a shorter duration of activity than Levothyroxine.

The chief action of Levothyroxine is to increase the rate of cell metabolism.

INDICATION AND DOSE:

Hypothyroidism

Adult 18–49 years: Initially 50–100 micrograms once daily; adjusted in steps of 25–50 micrograms every 3–4 weeks, adjusted according to response; maintenance 100–200 micrograms once daily, dose to be taken preferably at least 30 minutes before breakfast, caffeine-containing liquids (e.g., coffee, tea), or other medication

Adult 50 years and over: Initially 25 micrograms once daily; adjusted in steps of 25 micrograms every 4 weeks, adjusted according to response; maintenance 50–200 micrograms once daily, dose to be taken preferably at least 30 minutes before breakfast,caffeine-containing liquids (e.g. coffee, tea), or other medication

Hypothyroidism in patients with cardiac disease | Severe hypothyroidism

Adult: Initially 25 micrograms once daily; adjusted in steps of 25 micrograms every 4 weeks, adjusted according to response; maintenance 50–200 micrograms once daily, dose to be taken preferably at least 30 minutes before breakfast, caffeine containing liquids (e.g., coffee, tea), or other medication

Hyperthyroidism (blocking-replacement regimen) in combination with carbimazole

Adult: 50–150 micrograms daily therapy usually given for 18 months

CONTRA INDICATIONS:

Hypersensitivity to active substance or to any of the excipients listed in section Thyrotoxicosis. Adrenal gland disorder or adrenal insufficiency.

CAUTIONS:

Cardiovascular disorders. diabetes insipidus. diabetes mellitus (dose of antidiabetic drugs including insulin may need to be increased). elderly. hypertension. long-standing hypothyroidism. myocardial infarction. myocardial insufficiency. panhypopituitarism (initiate corticosteroid therapy before starting levothyroxine). predisposition to adrenal insufficiency (initiate corticosteroid therapy before starting levothyroxine)

CAUTIONS, FURTHER INFORMATION:

Cardiovascular disorders Baseline ECG is valuable because changes induced by hypothyroidism can be confused with ischaemia.

SIDE EFFECTS:

Angina pectoris. anxiety. arrhythmias. arthralgia. diarrhoea. dyspnoea. fever. flushing. headache. hyperhidrosis. insomnia. malaise. menstruation irregular. muscle spasms. muscle weakness oedema. palpitations. skin reactions. thyrotoxic crisis. tremor. vomiting. weight decreased.

SIDE-EFFECTS, FURTHER INFORMATION:

Initial dosage in patients with cardiovascular disorders If metabolism increases too rapidly (causing diarrhoea, nervousness, rapid pulse, insomnia, tremors and sometimes anginal pain where there is latent myocardial ischaemia), reduce dose or withhold for 1–2 days and start again at a lower dose.

USE IN PREGNANCY:

Levothyroxine may cross the placenta. Excessive or insufficient maternal thyroid hormones can be detrimental to fetus. Dose adjustments Levothyroxine requirement may increase during pregnancy. Monitoring Assess maternal thyroid function before conception (if possible), at diagnosis of pregnancy, at antenatal booking, during both the second and third trimesters, and after delivery (more frequent monitoring required on initiation or adjustment of levothyroxine).

BREAST FEEDING:

Amount too small to affect tests for neonatal hypothyroidism.

HEPATIC IMPAIRMENT:

Not more than 20 mg daily should be needed.

INTERACTION:

Reduced absorption with iron, antacids, bile acid sequestrants, colestyramine, simeticone, Ca carbonate, sucralfate, cation exchange resins. Reduced tri-iodothyronine serum levels with amiodarone and propranolol. Reduced serum levels with carbamazepine, phenytoin, phenobarbital, rifampicin, lithium, oestrogens, sertraline. Androgens may decrease levothyroxine-binding globulins serum levels. May alter requirements of antidiabetic drugs. Increased risk of significant HTN and tachycardia with ketamine. Increased metabolic demands with sympathomimetics (e.g., epinephrine). May increase anticoagulant effect of warfarin.

FOOD INTERACTION:

Decreased bioavailability and lower serum levels with enteral nutrition. Reduced absorption with food, soybean infant formula, cottonseed meal, walnuts and dietary fiber.

ADMINISTRATION:

Should be taken on an empty stomach. Take 30 min-1 hr. before meals.

MONITORING PARAMETERS:

Monitor thyroid function test, clinical signs of hypo- and hyperthyroidism, heart rate and BP.

OVERDOSAGE:

Symptoms: Increased BP, fever, tachycardia, agitation, arrhythmias, anxiety states, hyperkinesis, confusion, neurological complications and coma.

Management: Use of activated charcoal and a β-blocker (e.g., propranolol or metoprolol) for tachyarrhythmia. Symptomatic and supportive treatment must also be applied.

STORAGE:

Keep tightly closed in cool and dry place below 30°C. Store in the original package in order to protect from light and moisture.

Keep all medicines away from children.

Manufactured by:
State Pharmaceuticals Manufacturing Corporation
No. 11, Sir John Kotalawala Mawatha, Kandawala Estate, Ratmalana, Sri Lanka.