Thynor®

Levothyroxine Sodium BP tablet

DESCRIPTION

Thynor® is preparation of Levothyroxine Sodium. Levothyroxine (T4) is a naturally occurring hormone produced by the thyroid gland and converted to the more active hormone tri-iodothyronine (T3) in peripheral tissues. The thyroid hormones are required for normal growth and development, particularly of the nervous system. They increase the resting or basal metabolic rate of the whole organism and have stimulatory effects on the heart, skeletal muscle, liver and kidney. Thyroid hormones enhance lipolysis and the utilization of carbohydrate.

INDICATIONS

Recommended clinical indications: Control of hypothyroidism, congenital hypothyroidism and juvenile myxoedema.

DOSAGE AND ADMINISTRATION

Levothyroxine tablets should be taken on an empty stomach, preferably before breakfast.

Adults: Initially 50 to 100 micrograms daily and adjust at 3 to 4 weeks intervals by 50 micrograms until normal metabolism is steadily maintained. This may require doses of 100 to 200 micrograms daily.

Elderly: For patients over 50 years, it is not advisable to exceed 50 micrograms daily initially and where there is cardiac disease, 25 micrograms daily or 50 micrograms on alternate days is more suitable initially. In this condition the daily dose may be increased by 25 micrograms at intervals of perhaps 4 weeks.

Children: For children with acquired hypothyroidism, the initial recommended dosage is 12.5-50 micrograms per day. The dose should be increased gradually every 2 to 4 weeks according to the clinical findings and thyroid hormone and TSH values until the full replacement dose is reached.

In congenital hypothyroidism and juvenile myxoedema, the largest dose consistent with freedom from toxic effects should be given. The dosage is guided by clinical response, growth assessment and appropriate thyroid function tests - clinically normal pulse rate and absence of diarrhoea or constipation are the most useful indicators. Tyrotrophin levels may remain elevated during the first year of life in children with neonatal hypothyroidism due to resetting of the hypothalamic-pituitary axis.

When applicable:

Tablets are to be disintegrated in some water (10 to 15 ml) and the resultant suspension, which must be prepared freshly as required, is to be administered with some more liquid (5 to 10 ml).

Neonates and Infants: For neonates and infants with congenital hypothyroidism, where rapid replacement is important, the initial recommended dosage is 10 to 15 micrograms per kg body weight per day for the first 3 months. Thereafter, the dose should be adjusted individually according to the clinical findings and thyroid hormone and TSH values.

Infants should be given the total daily dose at least half an hour before the first meal of the day.

CONTRAINDICATIONS

- Hypersensitivity to active component of the preparation
- Thyrotoxicosis.

SPECIAL WARNINGS AND PRECAUTIONS

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. Levothyroxine sodium should be used with caution in patients with cardiovascular disorders, including angina, coronary artery disease, hypertension, and in the elderly who have a greater likelihood of occult cardiac disease.

Thyroid replacement therapy may cause an increase in dosage requirements of insulin or other anti-diabetic therapy. Care is needed for patients with diabetes mellitus, and diabetes insipidus.

Subclinical hyperthyroidism may be associated with bone loss. 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.

UNDESIRABLE EFFECTS

Side-effects are usually indicative of excessive dosage and usually disappear on reduction of dosage or withdrawal of treatment for a few days. Such effects include:

General: Headache, flushing, fever and sweating

Immune system disorders: hypersensitivity reactions including rash, pruritus and oedema

Metabolic: weight loss

Nervous system: tremor, restlessness, excitability, insomnia. Rarely, benign intracranial hypertension in children.

Cardiac: anginal pain, cardiac arrythmias, palpitations, tachycardia

Gastrontestinal: diarrhoea, vomiting

Musculoskeletal and connective tissue: muscle cramps, muscle weakness, craniostenosis in infants and premature closure of epiphysis in children.

Reproductive: menstrual irregularities

Heat intolerance, transient hair loss in children, also reported.

USE IN PREGNANCY AND LACTATION

Pregnancy: Levothyroxine has been taken by a large number of pregnant women and women of childbearing age without any form of definite disturbances in the reproductive process having been observed so far. Thyroid hypo- or hyperactivity in the mother may, however, unfavorably influence the fetal outcome or well-being.

Lactation: Levothyroxine is excreted in breast milk in low concentrations and this may be sufficient to interfere with neonatal screening for hypothyroidism.

OVERDOSE

In addition to exaggeration of side effects the following symptoms may be seen: agitation, confusion, irritability, hyperactivity, headache, sweating, mydriasis, tachycardia, arrhythmias, tachypnoea, pyrexia, increased bowel movements and convulsions. The appearance of clinical hyper-thyroidism may be delayed for up to five days.

Gastric lavage or emesis is required if the patient is seen within several hours of taking the dose.

Treatment is symptomatic, and tachycardia has been controlled in adults by 40 mg doses of propranolol given every 6 h and other symptoms by diazepam and/or chlorpromazine as appropriate.

INTERACTIONS

Interactions affecting other drugs:

Levothyroxine increases the effect of anticoagulants and it may be necessary to reduce the dose of anticoagulant if excessive, hypoprothrombinaemia and bleeding are to be avoided.

Blood sugar levels are raised and dosage of anti-diabetic agents may require adjustment.

Tricydic anti-depressants response may be accelerated because levothyroxine increases sensitivity to catecholamines; concomitant use may precipitate cardiac arrhythmias.

The effects of sympathomimetic agents (e.g. adrenaline) are also enhanced

If levothyroxine therapy is initiated in digitalised patients, the dose of digitalis may require adjustment. Hyperthyroid patients may need their digoxin dosage gradually increased as treatment proceeds because initially patients are relatively sensitive to digoxin.

Propranolol: levothyroxine (thyroxine) accelerates metabolism of propranolol.

Isolated reports of marked hypertension and tachycardia have been reported with concurrent ketamine administration.

PHARMACEUTICAL PRECAUTION

Keep in dry place and away from light. Keep out of reach of children.

PACKAGING

Thynor® tablet: Box containing 9 strips of 10 tablets each. Each tablet contains Levothyroxine Sodium BP 50 mcg.

SK+F
Manufactured for
ESKAYEF BANGLADESH LIMITED
By POPULAR PHARMACEUTICALS LTD.
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