

Thyro³ Tablet



Alpha · Pharma
healthcare

GENERIC NAME

Liothyronine Tablet

CHEMICAL NAME

2-amino-3-[4-(4-hydroxy-3-iodo-phenoxy)-3,5-diiodo-phenyl]-propanoic acid

MOLECULAR STRUCTURE

C₁₅H₁₂I₃NO₄

MOLECULAR WEIGHT

650.974 g/mol

PROPRIETARY NAME Thyro³ Tablet

DOSAGE FORM

25 mcg Liothyronine tablet for oral administration

COMPOSITION

Liothyronine: Each tablet contains liothyronine equivalent to 25 mcg liothyronine.

PHARMACOLOGICAL CLASSIFICATION

Thyroid Hormone

PHARMACOLOGICAL ACTION

Thyroid gland secretes L thyroxin (T₄) and triiodothyronine (T₃). T₃ is the major physiologically active natural thyroid hormone. It's about 3 to 4 times more potent than T₄. Iodine is utilized for synthesis of thyroid hormone from iodides. Iodide is concentrated in thyroid epithelial cells (iodide trap). This is oxidized to iodine its iodination takes place to form monoiodothyrosine (MIT) and diiodothyrosine (DIT). Tri-iodothyronine is formed by coupling of one molecule of MIT with one molecule of DIT Whereas tri-iodothyronine is formed by coupling of two molecules of DIT.

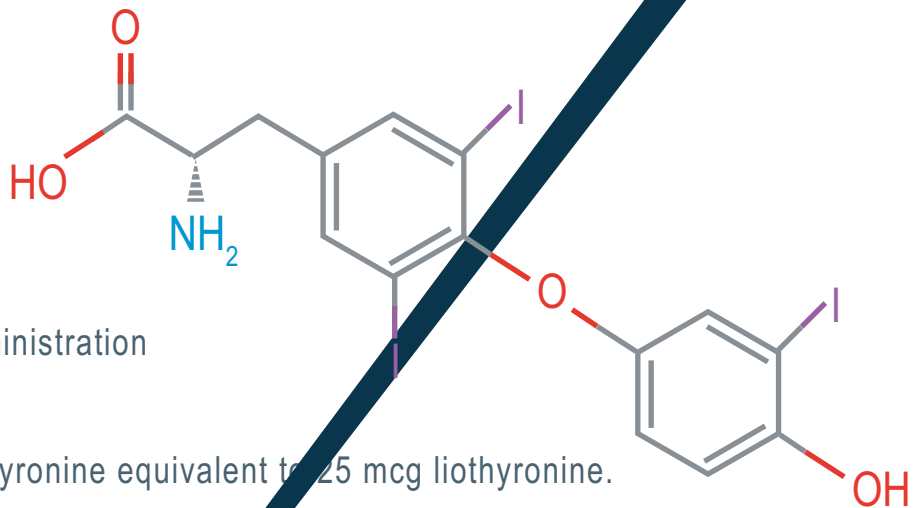
Thyroid hormones play an important role in body affecting some of the fundamental processes such as oxygen consumption, heat production, and metabolism of carbohydrates, proteins and fats. Severe hypothyroidism in adults is called myxedema and cretinism in children.

PHARMACOKINETICS

Thyro³ tablet (T₃) is readily absorbed after oral administration. About 5% of endogenous organic iodine in the blood is in the form of liothyronine and normal plasma concentrations are about 70ng/mL.

Thyro³ tablet is highly bound in plasma but to a lesser extent than thyroxin. It has a plasma half-life of about 35 to 60 hours.

Liothyronine is widely distributed throughout the body tissues and fluids and is subject to enterohepatic circulation. It does not cross the placenta or to be secreted into the breast milk. Liothyronine is excreted mainly in the bile and faeces although iodide may be excreted in the urine.



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INDICATIONS

Thyro³ Tablet is used to treat hypothyroidism, in adults and children.

Prolonged hypothyroidism can result in a condition called myxedema in which patients develop swollen lips, thickened nose, and unusual deposits of material in the skin that are dry and waxy. Thyro³ Tablet also is used as diagnostic aid in a test of the thyroid gland to determine if the thyroid is functioning normally.

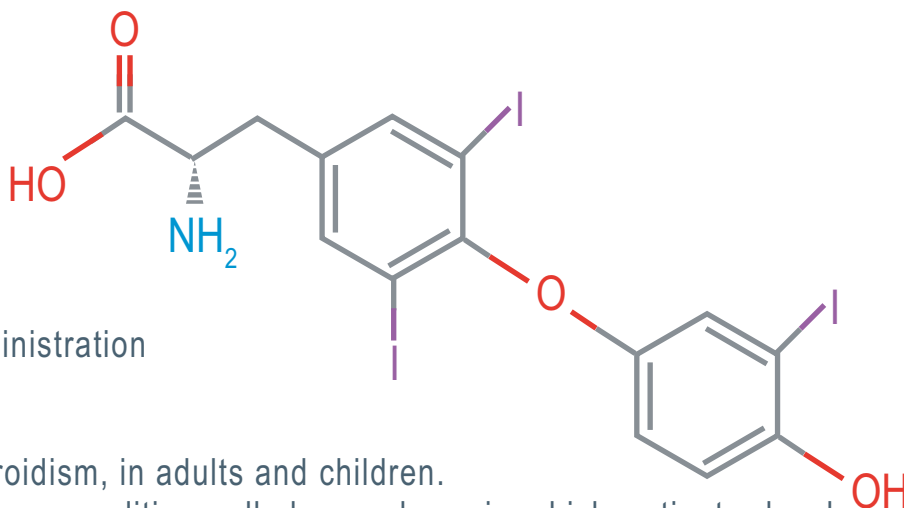
It is used in the treatment of various types of euthyroid goiters, including sub-acute thyroid nodules or chronic lymphocytic thyroiditis (Hashimoto's), multinodular goiter and papillary carcinoma of thyroid.

DOSAGE & ROUTE OF ADMINISTRATION:

Thyro³ tablets are intended for oral administration once-a-day dosage before breakfast is recommended.

ADULTS:

- Thyroid deficiency, the initial dose is 10 or 20mcg every 8 hours then the dose is increased after one week to the usual recommended dosage of 60mcg daily in divided doses. In the treatment of thyrotoxicosis with carbimazole, 20mcg of liothyronine should be given every 8 hours.
- Mild Hypothyroidism: Recommended dosage is 25 mcg daily. Daily dosage may be increased by up to 25 mcg every 1 or 2 weeks. Usual maintenance dose is 25 to 75 mcg daily.
- Myxedema: Recommended starting dosage is 5 mcg daily. It may increase by 5 to 10 mcg daily every 1 or 2 weeks. When 25 mcg daily is reached, dosage may be increased by 5 to 25 mcg every 1 or 2 weeks until a satisfactory therapeutic response is attained. Usual maintenance dose is 50 to 100 mcg daily.
- Simple (non-toxic) Goiter: Recommended starting dosage is 5 mcg daily. Dosage may be increased by 5 to 10 mcg daily every 1 or 2 weeks. When 25 mcg daily is reached, dosage may be increased every week or two by 12.5 or 25 mcg. Usual maintenance dosage is 75 mcg daily.



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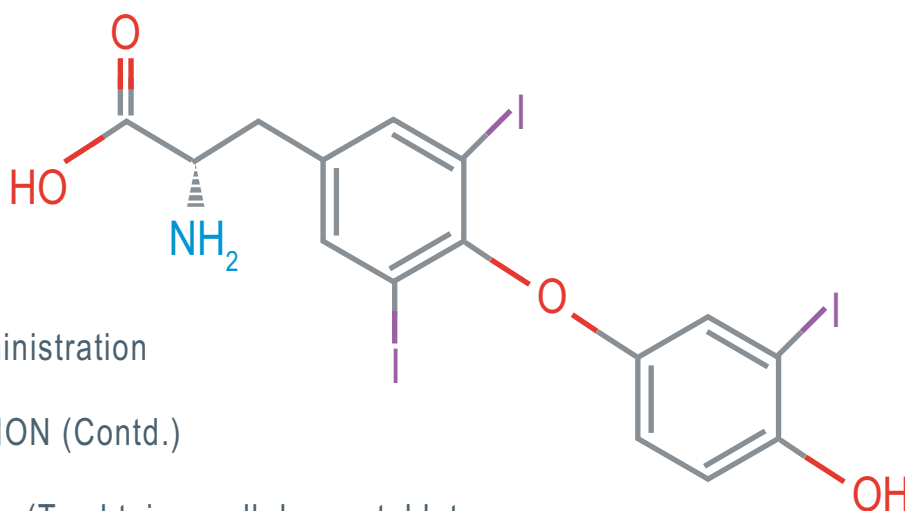
25 mcg Liothyronine tablet for oral administration

DOSAGE & ROUTE OF ADMINISTRATION (Contd.)

For children and elderly patients:

The initial dosage should be 5mcg daily. (To obtain small doses, tablets may be crushed and triturated with lactose for administration as a powder).

Thyro³ Tablet should be given in divided doses two or three times daily.



OVER DOSAGE

Gastric lavage or emesis is required if the patient is seen within a few hours of taking the dose. In addition to exaggeration of side effects the following symptoms may be seen: agitation, confusion, irritability, hyperactivity, headache, sweating, mydriasis, tachycardia, arrhythmias, tachypnoea, pyrexia, increase bowel movements and convulsions.

Treatment is symptomatic; tachycardia has been controlled in adults by 40mg doses of propranolol given every six hours.

SIDE EFFECTS

Allergic reaction (difficulty breathing, losing of the throat; swelling of the lips, tongue, or face), vomiting, chest pain, irregular heartbeat, or shortness of breath.

Other, less serious side effects may be tremor, nervousness, or irritability, headache, insomnia, diarrhea, weight loss, leg cramps, menstrual irregularities, fever, sweating, or heat sensitivity

WARNINGS:

Thyroid hormone should not be used to treat obesity in patients with normal thyroid function. Liothyronine is ineffective for weight reduction in normal thyroid patients and may cause serious or life-threatening toxicity, especially when taken with amphetamines.

DRUG INTERACTIONS:

Oral Anticoagulants: Thyro³ Tablet therapy may potentiate the effect of anticoagulants.

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DRUG INTERACTIONS: (Contd.)

Anticonvulsants: Such as carbamazepine and phenytoin enhance the metabolism of thyroid hormones and may displace them from plasma proteins.

Insulin or Oral Hypoglycemic: Initiating thyroid replacement therapy may cause increases in insulin or oral hypoglycemic requirements. Patients receiving insulin or oral hypoglycemic should be closely monitored during initiation of thyroid replacement therapy.

Estrogen, Oral Contraceptives: Co-administration of oral contraceptives may result in an increased dosage requirement of liothyronine sodium.

Tricyclic Antidepressants: concurrent administration with imipramine and other tricyclic antidepressants may increase receptor sensitivity, enhance antidepressant activity and thyroid hormone activity; transient cardiac arrhythmias have been observed.

Digitalis: Thyroid preparations may potentiate the toxic effects of digitalis.

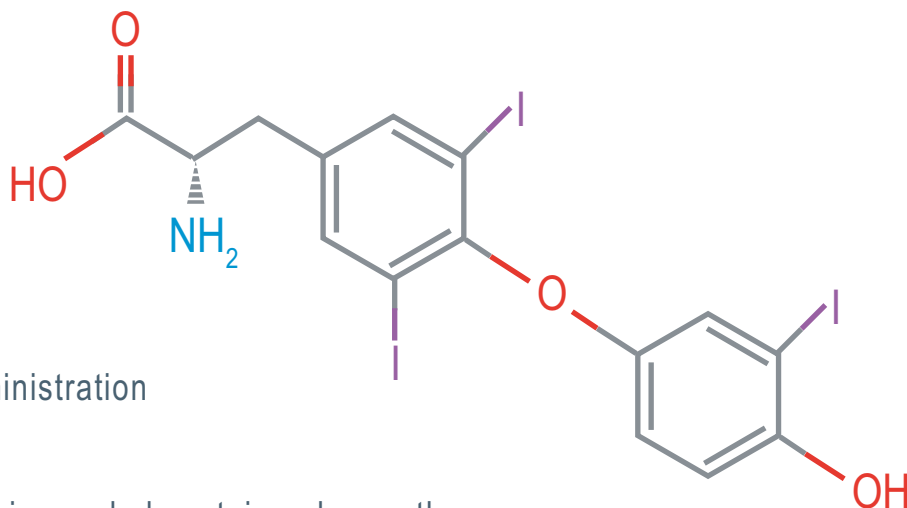
Ketamine: concurrent administration of liothyronine with parenteral anaesthetic, ketamine may cause hypertension and tachycardia.

Cholestyramine: Concurrent administration of liothyronine with cholestyramine reduces gastrointestinal absorption of liothyronine.

Vasopressors: Use of vasopressors in patients receiving liothyronine may increase the risk of precipitating coronary insufficiency, especially in patients with coronary artery disease.



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PRECAUTIONS

In severe and prolonged hypothyroidism, adrenocortical activity may be decreased which can lead to adrenocortical insufficiency. Supplemental adrenocortical steroids may be necessary.

Thyroid replacement therapy may aggravate diabetes mellitus and result in an increase in dosage requirement of insulin or other antidiabetic therapy.

In myxoedema, care must be taken to avoid imposing excessive burden on cardiac muscle affected by prolonged severe thyroid depletion.

CONTRAINDICATIONS

Thyro³ Tablet is contraindicated in Thyrotoxicosis.

Thyro³ Tablet should not be used in patients with known hypersensitivity to drug or any of its excipients. Thyro³ tablet is contraindicated in patients with cardiovascular disorders or angina.

Pregnancy and lactating mother:

Thyroid hormones does not cross the placental barrier therefore thyroid replacement therapy should not be discontinued to hypothyroid women during pregnancy.

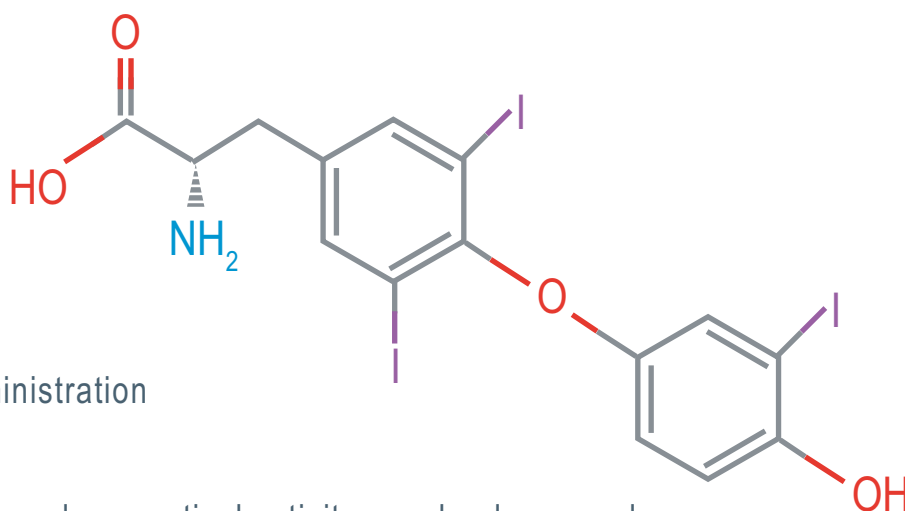
Liothyronine is excreted in breast milk in low concentrations. Thyroid is not associated with serious adverse reactions and does not have a known tumorigenic potential. However, caution should be taken when Thyro³ is administered to lactating mothers.

PRESENTATION

100 tablets in a light amber bottle with Silver cap. The amber bottle is placed in a monocarton along with leaflet. Pink color tablet with Cap tab shape having embossing of 25 mcg and T3 respectively on either side of tablet.



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STORAGE

Store at room temperature (below 25°C). Protect from light.

MARKETED BY

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