METAPHARMACEUTICAL

TECHNICAL DATA SHEET

002462-TDS-ENG-2026

LIOTIRONINA SODICA T3 (EUR. PH.)		
DESCRIPTION DCI: LIOTHYRONINE SODIUM	DESCRIPTION DOE: LIOTIRONINA SODICA	
CAS Nº: 55-06-1	EC Nº: 200-223-5	AEMPS CODE: 1853SO
MOL. WEIGHT: 673,0	MOL. FORMULA: C15H11I3NNaO4	ARTICLE CODE: 002462

ATTRIBUTES	SHOULD BE
Appearance	White or slightly coloured, hygroscopic powder
Solubility	Practically insoluble in water, slightly soluble in ethanol (96 %). It dissolves in dilute solutions of alkali hydroxides
Identification A	Complies
Identification C	Complies
Identification E	Complies
Specific optical rotation	+18.0 / +22.0
Related substances	
Impurity A	=< 1.0 %
Impurity E	=< 0.5 %
Impurity B	=< 0.3 %
Impurity C	=< 0.3 %
Impurity D	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 2.0 %
Chlorides	=< 2.0 %
Loss on drying	=< 4.0 %
Assay	95.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 12.2

STORAGE

Keep the container tightly closed. Store between 2 - 8 ºC, protected from light.

REMARKS

Liothyronine Sodium is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

Properties and uses

The treatment of the oral route in the treatment of hypothyroidism and the therapy of metabolic insufficiency syndrome,

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and in the experimental form for the treatment of male sterility and menstrual disorders associated with hypothyroidism.
Its effect begins quickly, reaches its maximum in 1 - 3 days and disappears 3 days later. The intensity of its activity declines to half its original value in 4 - 10 days. It is less effective than levothyroxine in suppressing TSH release.
It is easily absorbed in the digestive tract and 30-40% can be recovered in the stool. It is very weakly expressed in plasma proteins and in the higher parts. It crosses the blood-brain barrier, not recommended for use in children. To minimize fluctuations in plasma concentration, it can be administered in 2 - 3 daily doses. Its half-life in plasma is between 1 - 2 days, prolonging with hypothyroidism and reducing with hyperthyroidism.
It is used in cases of thyroid insufficiency, such as goiter, cretinism, myxedema, hypothyroidism, obesity of hypothyroid origin, and comedosemic coma. It can be used to suppress goiter before surgery. It has also been qualified for the diagnosis of thyrotoxicosis in adults.

Dosage
The dosages, for the therapy of thyroid disorders, are usually individualized in the clinical response and in the regular monitoring.

Side effects
With small doses may be signs of hypothyroidism such as weakness, muscle pain, headache, weight gain, menstrual disorders, clumsiness, coldness and dry skin. Rarely, hypersensitivity reactions such as rashes.
At high doses, hyperthyroidism can occur with weight loss, anorexia, vomiting, diarrhea, headache, nervousness, sweating, palpitations, tachycardia and cardiac arrhythmias.

Contraindications
Thyrotoxicosis, adrenocortical or pituitary insufficiency, hyperthyroidism and cardiovascular diseases, such as angina pectoris, arteriosclerosis, hypertension, myocardial infarction and coronary insufficiency.

Precautions
In diabetic patients, glucose intolerance decreases. It should be administered with caution in patients with malabsorption syndromes, such as celiac.
Before any problem of aggravation of the cardiovascular clinical picture, it must be met with the dose, as well as in the mixture, long-term hypothyroidism and in old age, since they are more susceptible to the effects of thyroid hormone.
Periodically control the response of the individual.

Interactions
Alters the activity of oral anticoagulants, adjusting the dosage in the protombine time function.
It can modify the requirements of insulin and oral anticoagulants, and enhance the action of tricyclic and sympathomimetic antidepressants.
Cholestyramine can decrease the effect of thyroid hormones.

Formulation examples

Oral solution of SODIUM LYTOTIRONIN 7.5 mg/5 mL
SODIUM LYTOTIRONINE (1/1000 dilution in microcrystalline cellulose) - **0.15 g**
Glycerin - **0.5 mL**
Flavoring q.s.
Simple syrup - **50 mL**
Hiroxypropylmethylcellulose gel 1 - 3% c.s.p. - **100 mL**

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Modus operandi: Moisten the diluted LIOTIRONINE with a little glycerin in a mortar. Add the flavoring, the simple syrup, and adjust a final volume with the solution of hiroxipropilmetilcelulosa.
Approximate stability: 14 days in refrigerator.

SODIUM LYTOTIRONINE capsules
SODIUM LYTOTIRONINE - **5 mg**
for a **capsule n ° 50**

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