SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Iraksin 15 microgram Tablets

Liothyronine Sodium 15 microgram Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains liothyronine sodium 15 micrograms.

Excipient with known effect:
Each tablet contains 37.595 mg lactose (as lactose monohydrate).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

White to off white, circular biconvex, uncoated tablets, debossed with "L4" on one side and plain on other side, 5.5 mm diameter.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Liothyronine sodium is indicated in adults and children for the treatment of coma of myxoedema, the management of severe chronic thyroid deficiency and hypothyroid states occurring in the treatment of thyrotoxicosis.

Liothyronine sodium can be used also as an adjunct to carbimazole to prevent sub-clinical hypothyroidism developing during carbimazole treatment of thyrotoxicosis.

Liothyronine sodium may be preferred for treating severe and acute hypothyroid states because of its rapid and more potent effect, but thyroxine sodium is normally the drug of choice for routine replacement therapy.

4.2 Posology and method of administration

Posology

Adults:

Starting dose of 10 or 20 micrograms every 8 hours, increasing after one week, if necessary, to the usual recommended daily dose of 60 micrograms in two or three divided doses.

Myxoedema Coma:

60 micrograms given by stomach tube, then 20 micrograms every 8 hours. It is more usual to start treatment with intravenous liothyronine.

Adjunct to carbimazole treatment of thyrotoxicosis:

20 micrograms every 8 hours.

Paediatric population:

Children below 12 years:

A dose of 5 micrograms daily.

Adolescents: 12 – 17 years:

Initially 10-20 micrograms daily; increased to 60 micrograms daily in 2-3 divided doses.

Elderly:

A dose of 5 micrograms daily.

Method of administration

For oral use only.

Patients who have difficulty in swallowing a whole tablet, such as the elderly and young children, a whole tablet may be crushed and allowed to dissolve, with swirling, in a minimum 20 ml of water for 5 minutes. The entire volume of liquid should be consumed to ensure ingestion of the full dose.

Solubility of liothyronine in water enables this as a method of administration.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Patients with angina of effort or cardiovascular diseases and thyrotoxicosis.

4.4 Special warnings and precautions for use

In severe and prolonged hypothyroidism, adrenocortical activity may be decreased. When thyroid replacement therapy is started, metabolism increases more than adrenocortical activity and this can lead to adrenocortical insufficiency requiring supplemental adrenocortical steroids.

Liothyronine rather than levothyroxine would be the replacement therapy of choice during block and replace treatment of thyrotoxicosis with propylthiouracil (PTU) due to the inhibition by PTU of the peripheral conversion of T4 to T3.

Liothyronine sodium treatment may result in an increase in insulin or anti-diabetic drug requirements. Care is required for patients with diabetes mellitus and diabetes insipidus.

In myxoedema, care must be taken to avoid imposing excessive burden on cardiac muscle affected by prolonged severe thyroid depletion. Particular care is needed in the elderly who have a greater risk of occult cardiovascular disease. Baseline ECG is recommended prior to commencement of liothyronine treatment in order to detect changes consistent with ischaemia. Patients should undergo cardiovascular monitoring, including periodic ECGs, during liothyronine treatment. Liothyronine is contraindicated in established myocardial ischaemia (see section 4.3) in which case, levothyroxine, with cautious dose escalation, is recommended instead.

Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malabsorption should not take this medication.

Panhypopituitarism or predisposition to adrenal insufficiency (initiate corticosteroid therapy before starting liothyronine), pregnancy, breast-feeding (see section 4.6 Pregnancy and lactation).

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 1-2days and start again at a lower dose.

TSH levels should be monitored during treatment to reduce the risk of over- or under-treatment. The risks of over-treatment include atrial fibrillation, osteoporosis and bone fractures.

Interferences with laboratory test:

Biotin may interfere with thyroid immunoassays that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results. The risk of interference increases with higher doses of biotin.

When interpreting results of laboratory tests, possible biotin interference has to be taken into consideration, especially if a lack of coherence with the clinical presentation is observed.

For patients taking biotin-containing products, laboratory personnel should be informed when a thyroid function test is requested. Alternative tests not susceptible to biotin interference should be used, if available. (see section 4.5)

Information about ingredients

Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Liothyronine sodium therapy may potentiate the action of anticoagulants. Phenytoin levels may be increased by liothyronine. Anticonvulsants, such as carbamazepine and phenytoin enhance the metabolism of thyroid hormones and may displace thyroid hormones from plasma proteins. Initiation or discontinuation of anticonvulsant therapy may alter liothyronine dose requirements.

If co-administered with cardiac glycosides, adjustment of dosage of cardiac glycoside may be necessary. Cholestyramine and colestipol given concurrently reduces gastrointestinal absorption of liothyronine.

Liothyronine raises blood sugar levels and this may upset the stability of patients receiving antidiabetic agents.

Liothyronine increases receptor sensitivity to catecholamines thus accelerating the response to tricyclic antidepressants. A number of drugs may affect thyroid function tests and this should be borne in mind when monitoring patients on liothyronine therapy.

Co-administration of oral contraceptives may result in an increased dosage requirement of liothyronine sodium.

Amiodarone may inhibit the deiodination of thyroxine to triiodothyronine resulting in a decreased concentration of triiodothyronine with a rise in the concentration of inactive reverse triiodothyronine.

As with other thyroid hormones, Liothyronine may enhance effects of amitriptyline and effects of imipramine.

Metabolism of thyroid hormones accelerated by barbiturates and primidone (may increase requirements for thyroid hormones in hypothyroidism).

Requirements for thyroid hormones in hypothyroidism may be increased by oestrogens.

Interferences with laboratory test:

Biotin may interfere with thyroid immunoassays that are based on a biotin/streptavidin interaction, leading to either falsely decreased or falsely increased test results (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy:

Safety during pregnancy is not known. The risk of foetal congenital abnormalities should be weighed against the risk to the foetus of untreated maternal hypothyroidism.

Breast-feeding:

Liothyronine sodium is excreted into breast milk in low concentrations.

This may interfere with neonatal screening programmes.

Fertility

No human or animal data on the effect of active substance liothyronine on fertility are available.

4.7 Effects on ability to drive and use machines

Iraksin/Liothyronine Sodium tablets have no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following effects are indicative of excessive dosage and usually disappear on reduction of dosage or withdrawal of treatment for a day or two.
The undesirable effects are listed below by organ class and the following frequency convention:
Not known: frequency cannot be estimated from the available data

System Organ Class	Frequency	Adverse Events
Cardiac disorders	Not known	Anginal pain, cardiac arrhythmias, palpitations, tachycardia
Gastrointestinal Disorders	Not known	Diarrhoea, vomiting
General disorders and administration site conditions	Not known	Fever, flushing, fever and heat intolerance
Immune system disorders	Not known	Hypersensitivity reactions including rash, pruritus and oedema also reported.

Metabolism and nutrition disorders	Not known	Excessive loss of weight
Musculoskeletal and connective tissue disorders	Not known	Muscle cramps, muscular weakness
Nervous system Disorders	Not known	Headache, tremor
Psychiatric disorders	Not known	Restlessness, excitability, insomnia
Skin and subcutaneous tissue disorders	Not known	Sweating
Vascular disorders	Not known	Flushing

Paediatric population:

- Transient hair loss in children (Not Known)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms:

If patient is seen within a few hours of overdosage: gastric lavage or emesis.

There may be exaggeration of the side effects as well as agitation, confusion, irritability, hyperactivity, headache, sweating, mydriasis, tachycardia, arrhythmias, tachypnoea, pyrexia, increased bowel movements and convulsions.

Management:

Treatment is symptomatic. Tachycardia in adults may be controlled with 40mg propranolol every 6 hours.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Thyroid Hormones, ATC code: H03AA02

Mechanism of action

Liothyronine sodium is a naturally occurring thyroid hormone.

The biological action of Liothyronine sodium is quantitatively similar to that of Levothyroxine sodium, but the effects develop in a few hours and disappear within 24 to 48 hours of stopping treatment.

5.2 Pharmacokinetic properties

Absorption:

Liothyronine sodium is almost completely absorbed from the gastro-intestinal tract.

Distribution:

It is less readily bound to plasma proteins than thyroxine. About 0.5% is in the unbound form.

Elimination:

The half-life of liothyronine in euthyroidism is 1 to 2 days. Thyroid hormones do not readily cross the placenta. Minimal amounts are excreted in breast milk.

5.3 Preclinical safety data

No further relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate,
Partially pregelatinized maize starch,
Spray dried acacia,
Sodium chloride,
Magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package to protect from light.

6.5 Nature and contents of container

Aluminium foil (ALU/ALU) blisters containing 7, 10, 14, 20, 28, 30, 56, 60, 84, 90 and 112 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Morningside Healthcare Limited
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Leicester, LE19 1WP
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8 MARKETING AUTHORISATION NUMBER(S)

PL 20117/0464

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/08/2025

10 DATE OF REVISION OF THE TEXT

12/08/2025