

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Triiodothyronine 20 Micrograms Powder For Solution For Injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Liothyronine Sodium 20 micrograms

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for solution for injection.
White freeze-dried powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

It is indicated for the treatment of myxoedema coma, usually in conjunction with other measures including the intravenous injection of a corticosteroid.

For the treatment of less severe forms of myxoedema and for maintenance therapy, orally administered liothyronine should be used.

4.2 Posology and method of administration

Dosage: 5 to 20 micrograms given by slow intravenous injection, and repeated at intervals of 12 hours or less if required. The minimal interval between dosing is 4 hours.

An initial dose of 50 micrograms intravenously is used by some physicians, followed by further intravenous injections of 25 micrograms every 8 hours until improvement occurs. The dosage may then be reduced to 25 micrograms intravenously twice daily.

Method of administration: Usually given by intravenous injection, as the alkalinity of the solution may cause irritation of the tissues if given by deep intramuscular injection. The solution is prepared by adding 1 or 2ml water for injection to the ampoule, and shaking gently until the solution has dissolved.

4.3 Contraindications

Hypersensitivity to any components of the preparation. Liothyronine sodium is contraindicated in patients with cardiovascular disorders or angina of effort.

4.4 Special Warnings and Precautions for Use

Liothyronine must be given with extreme caution in myxoedema coma because too large a dose can precipitate heart failure, especially in the elderly patients and those with ischaemic heart disease. ECG monitoring can give a useful indication of impending ischaemia; however, changes in ST segment can be confused with similar changes occurring in hypothyroidism, there may be increased adrenocortical activity. When thyroid replacement therapy is started, metabolism is raised at a greater rate than adrenocortical activity, and this can result in adrenocortical insufficiency. This insufficiency may require supplemental adrenocortical steroids.

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

Liothyronine should always be used with caution and under appropriate specialist supervision with adequate monitoring. Particular care is required in the elderly.

4.5 Interaction with other medicinal products and other forms of interactions

Liothyronine sodium therapy may potentiate the action of anticoagulants. 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. Phenytoin levels may be increased by liothyronine.

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

If co-administered with cardiac glycosides, adjustment of dosage of cardiac glycoside may be necessary.

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.

4.6 Pregnancy and Lactation

Pregnancy:

The safety of liothyronine during pregnancy is not known. Any possible risk of congenital abnormalities must be weighed against the risk to the foetus of untreated hypothyroidism in the mother.

Lactation:

Liothyronine is excreted into breast milk in low concentration. This may interfere with neonatal screening programmes.

4.7 Effects on Ability to Drive and Use Machines

None.

4.8 Undesirable Effects

The following are indicative of overdosage, and disappear after reduction of dosage or stopping treatment for a day or more:

Anginal pain, cardiac arrhythmias, palpitations, cramps, tachycardia, diarrhoea, restlessness, excitability, headache, flushing, sweating, excessive loss of weight and muscular weakness.

4.9 Overdose

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

Treatment is symptomatic. In adults, tachycardia has been controlled by 40mg propranolol every six hours.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Liothyronine (L-triiodothyronine) is a naturally occurring thyroid hormone. Its biological action is qualitatively similar to that of thyroxine, but the effect is more rapid in onset (in a few hours) and the effect disappears within 24 to 48 hours after stopping treatment.

5.2 Pharmacokinetic Properties

Liothyronine is less readily bound to plasma proteins than thyroxine, and about 0.5% exists in the unbound form. The half-life in the blood is about one to two days in euthyroidism.

Thyroid hormones do not readily cross the placenta. Minimal amounts are reported excreted in breast milk.

5.3 Preclinical Safety Data

No additional data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Dextran 110 freeze dried
Sodium Hydroxide

6.2 Incompatibilities

In absence of incompatibility studies, this medicinal product must not be mixed with other medicinal products

6.3 Shelf Life

12 months.

Reconstituted product should be used immediately and any unused portion should be discarded.

6.4 Special Precautions for Storage

Store below 25°C. Protect from Light.

6.5 Nature and Contents of Container

5ml Type I clear glass vial with siliconised bromobutyl rubber stopper, aluminium seal and red flip-off cap.
Pack size: 5 vials per carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only. Any unused contents must be discarded.
Reconstituted with water for injections.

7. MARKETING AUTHORISATION HOLDER

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Trading as Goldshield Pharmaceuticals.

8. MARKETING AUTHORISATION NUMBER

PA 701/2/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorization: 19 October 1993

Date of last renewal: 19 October 2008

10. DATE OF REVISION OF THE TEXT

30 June 2010