

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Tertroxin Tablets 20mcg

Liothyronine Sodium BP 20micrograms Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20mcg liothyronine sodium BP.

3. PHARMACEUTICAL FORM

Tablets

4. Clinical Particulars

4.1 Therapeutic indications

Tertroxin tablets are qualitatively similar in biological action to thyroxine but the effect develops in a few hours and lasts for 24 to 48 hours after stopping the treatment.

Used for the treatment of coma of myxedema, the management of severe chronic thyroid deficiency and hypothyroid states occurring in the treatment of thyrotoxicosis.

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

Tertroxin 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

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.

Myxedema 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.

Elderly and Children Patients: 5 micrograms daily (Tertroxin tablets can be crushed and triturated with lactose for administration as a powder).

Method of Administration: Oral

4.3 Contraindications

Hypersensitivity to any components of Tertroxin tablets.
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.

Tertroxin 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 myxedema, care must be taken to avoid imposing excessive burden on cardiac muscle affected by prolonged severe thyroid depletion. Care is needed in the elderly.

Patients with rare hereditary problems of galactose intolerance, the Lapp 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).

Baseline ECG is valuable with initial dosage because changes induced by hypothyroidism can be confused with ischaemia. 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 1-2 days and start again at a lower dose.

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. Colestyramine 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.

4.6 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.

Lactation:

Tertroxin is excreted into breast milk in low concentrations.

This may interfere with neonatal screening programmes.

4.7 Effects on ability to drive and use machines

None.

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. Anginal pain, cardiac arrhythmias, palpitations, muscle cramps, tachycardia, diarrhoea, restlessness, excitability, headache, flushing, sweating, excessive loss of weight and muscular weakness, vomiting, tremor, insomnia, fever, heat intolerance, transient hair loss in children, hypersensitivity reactions including rash, pruritus and oedema also reported.

4.9 Overdose

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.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Tertroxin (liothyronine sodium) is a naturally occurring thyroid hormone. The biological action of Tertroxin 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

Liothyronine sodium is almost completely absorbed from the gastro-intestinal tract. It is less readily bound to plasma proteins than thyroxine. About 0.5% is in the unbound form.

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 BP
Maize starch BP
Acacia powder BP
Sodium chloride BP
Magnesium stearate BP
Industrial methylated spirit BP
Purified water BP

6.2. Incompatibilities

None stated.

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Protect from light.

6.5. Nature and contents of container

Tubular glass vial with snap-plug closure or tamper-evident polypropylene container with polythene lid, containing 28, 56, 112 and 100 tablets of Tertroxin 20mcg.

6.6. Instruction for use, handling and disposal

None.

7 MARKETING AUTHORISATION HOLDER

Goldshield Group Limited
NLA Tower,
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CR0 0XT
Trading as Goldshield Pharmaceuticals

8. MARKETING AUTHORISATION NUMBER

PL 10972/0033

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF
AUTHORISATION**

06 November 1998

10 DATE OF REVISION OF THE TEXT

21/05/2011