SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Liothyronine sodium 20 microgram Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 micrograms of liothyronine sodium.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

White, biconvex, round tablets embossed “L20” on one side and plain on the other.

Dimensions: Approx. 6 mm diameter.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Liothyronine 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.

Elderly and paediatric population: 5 micrograms daily.

Method of administration

Oral

Where a dose of 5 micrograms or 10 micrograms is required, the following procedure is recommended to ensure that the active substance liothyronine is adequately dispersed. Note that the excipients do not dissolve as readily and therefore the suspension will remain cloudy.

Recommended dose 5 micrograms:

1) Crush one Liothyronine sodium 20 microgram tablet.
2) Transfer the crushed tablet to a 30 ml graduated medicine (dosing) cup containing 20 ml of water and leave to disperse for 5 minutes.
3) Gently stir the suspension for 15 seconds and then withdraw 5 ml of the suspension with an oral medicine (dosing) syringe.
4) The contents of the syringe may be emptied directly into the mouth by slowly pushing down the plunger of the syringe.

Any remaining liquid should be discarded immediately.

Recommended dose 10 micrograms:

1) Crush one Liothyronine sodium 20 microgram tablet.
2) Transfer the crushed tablet to a 30 ml graduated medicine (dosing) cup containing 20 ml of water and leave to disperse for 5 minutes.
3) Gently stir the suspension for 15 seconds and then withdraw 10 ml of the suspension with an oral medicine (dosing) syringe.
4) The contents of the syringe may be emptied directly into the mouth by slowly pushing down the plunger of the syringe.

Any remaining liquid should be discarded immediately.

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 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.

Liothyronine should be used with caution in patients with cardiovascular disorders, including angina, coronary artery disease, hypertension, and in the elderly who have a greater likelihood of occult cardiac disease.

In myxodema, 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.

Panhypopituitarism or predisposition to adrenal insufficiency (initiate corticosteroid therapy before starting liothyronine), pregnancy, breast-feeding (see section 4.6 Fertility, 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 1-2 days and start again at a lower dose.

Thyroid function should continue to be monitored throughout treatment to avoid over- or under-treatment. The risks of over-treatment include atrial fibrillation, osteoporosis and bone fractures.

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 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 and animal data on the effect of active substance liothyronine on fertility are available.

4.7 Effects on ability to drive and use machines

Liothyronine sodium has 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. 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.

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 the Yellow Card Scheme Website at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

If patient is seen within a few hours of overdose: 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 40 mg propranolol every 6 hours.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Thyroid preparations, thyroid hormones, ATC code: H03AA02

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 euthroidism 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

Microcrystalline cellulose

Maize starch

Pregelatinised starch

Silica, colloidal anhydrous

Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

1 year

6.4 Special precautions for storage

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

6.5 Nature and contents of container

OPA/Alu/PE-Aluminium blisters with desiccant containing 28 tablets.

HDPE bottles with PP cap including silica gel containing 28 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

TEVA UK Limited

Brampton Road

Hampden Park

Eastbourne

BN22 9AG

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/2116

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/08/2017

10 DATE OF REVISION OF THE TEXT

14/08/2017