IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0701/003/001
Case No: 2055773

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Goldshield Group Plc

NLA Tower, **12-16 Addiscombe Road, Croydon**, **CR0 OXT**, **England**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Tertroxin 20 microgram Tablets

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **23/10/2008** until **19/12/2008**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Tertroxin 20 microgram tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 20 Micrograms of liothyronine sodium.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Tablet
White uncoated tablet engraved on one side with ‘TERTROXIN’ and with a breakline on the reverse.

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 Myxoedema, 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.

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 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 disease.

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 myxodema, 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 lactose deficiency or glucose-galactose malabsorption should not take this medicine.

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 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.

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

Adverse reactions are listed by frequency:
Common >1/100, <1/10; Uncommon > 1/1,000, < 1/100; Rare > 1/10,000, < 1/1,000; Very rare < 1/10,000

The following effects are indicative of excessive dosage and usually disappear on reduction of dosage or withdrawal of treatment for a day or two.

Cardiac disorders
Very Rare: Cardiac signs and symptoms, tachycardia, palpitations

Nervous system disorders
Very Rare: headaches

Endocrine disorders
Very Rare: Hypothyroidism

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 propanolol every 6 hours.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: H03AA02

Pharmacotherapeutic group:
Systemic Hormonal Preparations, excluding Sex hormones and Insulins.

Tertroxin (liothyronine sodium) is a naturally occurring thyroid hormone.
The biological action of Tertroxin is quantitatively similar to that of Thyroxine, 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 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

Lactose
Maize Starch
Acacia Powder
Sodium Chloride
Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container.

6.5 Nature and contents of container

Tamper-evident polypropylene container with polythene lid, containing 100 tablets of Tertroxin 20micrograms.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Goldshield Group plc
12-16 Addiscombe Road
NLA Tower
Croydon CR0 OXT
England

8 MARKETING AUTHORISATION NUMBER

PA0701/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 December 1993

Date of last renewal: 20 December 2003

10 DATE OF REVISION OF THE TEXT

October 2008