SUMMARY OF PRODUCT CHARACTERISTICS
(SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Thiocal -12 Children Tonic

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Vitamin B1……. 2000mcg

Vitamin B2……. 1000mcg

Vitamin B6……. 2000mcg

Vitamin B12……. 5mcg

L –Lysine……..25mg

Liquid glucose…….750mg

Folic acid……..200mcg

Nicotinamide ……..15mg

Ferric Ammonium Citrate….25mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral Syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Thiocal 12 Children Tonic enhances healthy growth of kids. It serves as vitamin and iron supplement and also indicated in the treatment of prophylaxis of anaemia due to the deficiencies of iron, vitamin B12 or Folic acid. It improves appetite and optimal utilization of food intake and vitality of children.

4.2 Posology and method of administration

Age group 1 to 6years – Half teaspoonful (2.5ml) three times daily.
7 to 12years – One teaspoonful (5ml) two times daily.
Above 12 years: One teaspoonful (5ml) three times daily or as prescribe by the physician.

Method of Administration
Oral use

4.3 Contraindications

No Known sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use
Thiocal-12 Children Tonic should not be administered concurrently with milk products or antacids because of the formation of unabsorbable complexes with iron in Thiocal 12 Children Tonic. It may be administered one hour before or after taking milk products or antacids.

4.5 Interaction with other medicinal products and other forms of interaction
The pyridoxine hydrochloride may reduce the effectiveness of levodopa.

4.6 Pregnancy and lactation
Not Applicable.

4.7 Effects on ability to drive and use machines
None stated

4.8 Undesirable effects
At the recommended dose, Thiocal-12 Children Tonic is well tolerated by the body.

4.9 Overdose
Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Vitamin B Complex.

Thiamine Hydrochloride (Vit B1): A water soluble vitamin. It is a co-enzyme for carbohydrate metabolism.

Riboflavine Sodium Phosphate (Vit B2): A water soluble vitamin converted in the body to flavine mononucleotide and flavine adenine dinucleotide and then involved as co-enzymes in oxidative and reductive metabolic processes.

Nicotinamide: A water soluble vitamin considered part of the Vitamin B group. Converted to Nicotinamide Adenine Dinucleotide and Nicotinamide Adenine Dinucleotide Phosphate in the body, both of which are co-enzymes important in electron transfer in respiratory reactions.

Pyridoxine Hydrochloride (Vit B6): A water soluble vitamin. Involved in carbohydrate and fat metabolism, but also important in haemoglobin formation.

5.2 Pharmacokinetic properties
All the actives are water soluble vitamins. Quantities in excess of the bodies requirements are excreted either unchanged or as metabolites, mainly in the urine but to a lesser extent also in the faeces.

5.3 Preclinical safety data
None stated

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Granulated sugar, Citric Acid, Methyl paraben, Propyl paraben, Pineapple flavour, Sodium Hydroxide, Xanthan Gum, EDTA Sodium, Caramel

6.2 Incompatibilities
None known

6.3 Shelf life
36 months.

6.4. Special precautions for storage
Store at a temperature below 30°C away from direct sunlight.
Keep all medicines out of reach of children

6.5. Nature and content of outer packaging
100ml and 200ml PET bottle with measuring Cup.

6.6. Special precautions for disposal and other handling
Not applicable

7. Applicant
Therapeutic Laboratories Nig Ltd
372, Ikorodu Road, Maryland, Lagos.
08037266866, 07013485532.
regulatory.therapeutic@gmail.com