

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

THIOCAL -12 BLOOD TONIC

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Vitamin B1..... 2000mcg

Vitamin B2..... 1000mcg

Vitamin B6..... 2000mcg

Vitamin B12..... 5mcg

Nicotinamide 15mg

Folic Acid..... 300mcg

Ferric Ammonium Citrate....50mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral Syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

THIOCAL-12 BLOOD TONIC is indicated in the treatment of prophylaxis of iron deficiency and megaloblastic states of anaemia as in pernicious as well as in the deficiencies of vitamin B12 or Folic acid. The need for these compounds which may be referred to as heamatinic usually arise in case of pregnancy, lactation, nutritional deficiency, recovery from illness and even in chronic or severe hemorrhage due to accident, operation and child birth.

4.2 Posology and method of administration

posology

Adults- 2 teaspoonful (10ml) twice a day.

Children

Age group 7 to 12years – 1 teaspoonful (5ml) twice a day.

1 to 6years – ½ teaspoonful (2.5ml) twice a day.

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 Blood Tonic should not be administered concurrently with antacids, tetracycline or milk products because of the formation of unabsorbable complexes with iron contained in this product.

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

Considered safe in the recommended dose.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

At the recommended dose, Thiocal-12 Blood Tonic is well tolerated by the body in very rare cases or at high doses there could be gastro-intestinal discomfort, diarrhea, nausea and vomiting.

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, Liquid Glucose, Citric Acid, Methyl paraben, Propyl paraben, Sodium Hydroxide

6.2. Incompatibilities

Not applicable

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 container

100ml, 200ml, 250ml and 1Litre PET bottles 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.
therapeuticlaboratories@gmail.com

8. MANUFACTURER

Oak-Faith Pharmaceutical Resources Limited
10-12 Jalogun Palace Way, Imedu-Nla,
Mowe, Ogun State.
08033947016, 08023177024.
oakfaithpharma@gmail.com.