



Summary of Product  
Characterization  
(SMPC)  
of  
Dr. Wenger Advance Liquid  
Formula

## 1. Name of the medicinal product

Dr. Wenger Advance liquid Formula

## 2. Qualitative and quantitative composition

Each 10ml contains

Haemoglobin_____	250.00mg
Vitamin B1_____	1.00mg
Vitamin B2_____	1.00mg
Vitamin B3_____	5.00mg
Vitamin B6_____	0.50mg
Vitamin B12_____	40.00mcg
Vitamin A_____	100mcg
Vitamin D3_____	5.00mcg
Vitamin E_____	5.00mg
Vitamin B5_____	1.00mg
Biotin_____	50.00mcg
Zinc Gluconate_____	10.00mg
L-Carnithine_____	5.00mg
Lycopene_____	3.00mg
Potassium Iodide_____	80.00mcg
Magnesium glycinate _____	4.00mg
Green Tea_____	10.00mg
Ginseng _____	40.00mg
Ferric Ammonium Citrate_____	10.00mg
Coenzyme Q10_____	2.00mg
Choline bitartrate_____	2.50mg
Lutein_____	5.0mg

For the full list of excipients, see section 6.1.

## 3. Pharmaceutical form

Syrup

A brownish coloured syrup

## 4. Clinical particulars

### 4.1 Therapeutic indications

Multivitamin Syrup is indicated for the prevention of vitamin deficiencies and for the maintenance of normal growth and health during the early years of infancy and childhood; multivitamin supplement. 4.2 Posology and method of administration

### Dosage

**Adult:** 10ml to be taken twice daily

**Children: 5-12 years:** 5ml to be taken twice daily

## **Administration**

**Method of administration:** Oral

10ml daily, or as directed by the physician. Do not exceed recommended dose.

### **4.3 Contraindications**

Dr. Wenger Advance liquid must not be used in:

- hypersensitivity to the active substances, especially vitamin B1 or to any of the excipients listed in section 6.1
- hypervitaminosis from any vitamin contained in this formulation,

### **4.4 Special warnings and precautions for use**

Multivitamins are not recommended for the treatment of severe specific deficiencies of vitamins and minerals. While taking the multivitamins, both protein and energy are also required to provide complete nutrition in the daily diet. No other vitamins, minerals or supplements with or without vitamin A should be taken with this preparation except under medical supervision. Do not take on an empty stomach. Do not exceed the stated dose. Keep out of the reach of children. If symptoms persist, consult your doctor.

### **4.5 Interaction with other medicinal products and other forms of interaction**

Interactions between specific vitamins in Dr. Wenger Advance Liquid and other agents should be managed accordingly.

Such interactions include:

- Agents that can cause pseudotumor cerebri (including certain tetracyclines): Increased risk for pseudotumor cerebri by concomitant administration of Vitamin A
- Alcohol (chronic excessive consumption): Increases the risk of vitamin A hepatotoxicity
- Antiplatelet agents (e.g., aspirin): Vitamin E can add to the inhibition of platelet function
- Certain anticonvulsants (e.g., phenytoin, carbamazepine, phenobarbital, valproate): Can cause folate, pyridoxine and vitamin D deficiencies
- Certain antiretroviral agents: Decreased vitamin D levels have been associated with, e.g., efavirenz and zidovudine. Decreased formation of the active vitamin D metabolite has been associated with protease inhibitors.
- Chloramphenicol: Can inhibit the haematological response to vitamin B12 therapy
- Ethionamide: Can cause pyridoxine deficiency
- Levodopa: The content of pyridoxine may interfere with the effects of concurrent levodopa therapy.
- Pyridoxine antagonists, including cycloserine, hydralazine, isoniazid, penicillamine, phenelzine: Can cause pyridoxine deficiency

- Retinoids, including bexarotene: Increase the risk of toxicity when used concomitantly with vitamin A (see section 4.4: Hypervitaminosis A)
- Theophylline: Can cause pyridoxine deficiency
- Vitamin K antagonists (e.g., warfarin): Enhanced anticoagulant effect by vitamin E

#### 4.6 Fertility, pregnancy and lactation

Dr. Wenger Advance Liquid formula may be administered during pregnancy and lactation at the recommendation of the physician.

#### 4.7 Effects on ability to drive and use machines

There is no information on the effects of Dr. Wenger on the ability to operate an automobile or other heavy machinery.

#### 4.8 Undesirable effects

Generally multivitamin and multimineral are well tolerated by the body. Sometimes, reactions could occur, but they disappear rapidly after continuous and regular use. Ascorbic Acid (C), Nicotinamide, Pyridoxine (B6), Riboflavin (B2) & Thiamine (B1) These water-soluble vitamins are generally nontoxic compounds with a wide margin of safety, the excess amounts being rapidly excreted in the urine.

#### 4.9 Overdose

Seek emergency medical attention. Most commonly reported, symptoms of Vitamins & amino acid overdose include nausea and vomiting.

### 5. Pharmacological properties

#### 5.1 Pharmacodynamic properties

- (i) **Pharmaco-therapeutic group:** Multivitamins and other minerals, incl. combinations
- (ii) **ATC code:** A11AA03

**Mechanism of action:** Dr. Wenger is an Essential Amino Acids (Hemoglobin) & Vitamins Syrup. The pharmacokinetics of the active substances would not be different from those naturally derived by food orally.

The following account summarises the pharmacological effects of the vitamins and minerals in Dr. Wenger and describes the conditions caused by deficiency of these.

#### Vitamin A

Vitamin A plays an important role in the visual process. It is isomerised to the 11-cis isomer and subsequently bound to the opsin to form the photoreceptor for vision under subdued light. One of the earliest symptoms of deficiency is night blindness which may develop into the more serious condition xerophthalmia. Vitamin A also participates in the formation and maintenance of the integrity of epithelial tissues and mucous membranes. Deficiency may cause skin changes resulting in a dry rough skin with lowered resistance

to minor skin infections. Deficiency of Vitamin A, usually accompanied by protein-energy malnutrition, is linked with a frequency of infection and with defective immunological defence mechanisms.

### **Vitamin D**

Vitamin D is required for the absorption of calcium and phosphate from the gastrointestinal tract and for their transport. Its involvement in the control of calcium metabolism and hence the normal calcification of bones is well documented. Deficiency of Vitamin D in children may result in the development of rickets.

### **Vitamin B<sub>1</sub> (Thiamine)**

Thiamine (as the coenzyme, thiamine pyrophosphate) is associated with carbohydrate metabolism. Thiamine pyrophosphate also acts as a co-enzyme in the direct oxidative pathway of glucose metabolism. In thiamine deficiency, pyruvic and lactic acids accumulate in the tissues. The pyruvate ion is involved in the biosynthesis of acetylcholine via its conversion to acetyl co-enzyme A through a thiamine-dependent process. In thiamine deficiency, therefore, there are effects on the central nervous system due either to the effect on acetylcholine synthesis or to the lactate and pyruvate accumulation. Deficiency of thiamine results in fatigue, anorexia, gastro-intestinal disturbances, tachycardia, irritability and neurological symptoms. Gross deficiency of thiamine (and other Vitamin B group factors) leads to the condition beri-beri.

### **Vitamin B<sub>2</sub> (Riboflavine)**

Riboflavine is phosphorylated to flavine mononucleotide and flavine adenine dinucleotide which act as co-enzymes in the respiratory chain and in oxidative phosphorylation. Riboflavine deficiency presents with ocular symptoms, as well as lesions on the lips and at angles of the mouth.

### **Vitamin B<sub>6</sub> (Pyridoxine)**

Pyridoxine, once absorbed, is rapidly converted to the co-enzymes pyridoxal phosphate and pyridoxamine phosphate which play an essential role in protein metabolism. Convulsions and hypochromic anaemia have occurred in infants deficient in pyridoxine.

### **Vitamin B<sub>12</sub> (Cyanocobalamin)**

Vitamin B<sub>12</sub> is present in the body mainly as methylcobalamin and as adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerisation of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B<sub>12</sub> interferes with haemopoiesis and produces megaloblastic anaemia.

### **Vitamin E**

Vitamin E deficiency has been linked to disorders such as cystic fibrosis where fat absorption is impaired. It is essential for the normal function of the muscular system and the blood.

### **Nicotinamide**

The biochemical functions of nicotinamide as NAD and NADP (nicotinamide adenine dinucleotide phosphate) include the degradation and synthesis of fatty acids, carbohydrates and amino acids as well as hydrogen transfer. Deficiency produces pellagra and mental neurological changes.

### **Pantothenic Acid**

Pantothenic acid is incorporated into co-enzyme A and is involved in metabolic pathways involving acetylation which includes detoxification of drug molecules and biosynthesis of cholesterol, steroid hormones, mucopolysaccharides and acetylcholine. CoA has an essential function in lipid metabolism.

### **Vitamin H (d-Biotin)**

Biotin is a co-enzyme for carboxylation during the metabolism of proteins and carbohydrates.

### **Iron**

Iron, as a constituent of haemoglobin, plays an essential role in oxygen transport. It is also present in the muscle protein myoglobin and in the liver. Deficiency of iron leads to anaemia.

### **Magnesium (Magnesium glycinate)**

Magnesium is essential to the body as a constituent of skeletal structures and in maintaining cell integrity and fluid balance. It is utilised in many of the functions in which calcium is concerned but often exerts the opposite effect. Some enzymes require the magnesium ion as a co-factor.

### **Zinc (Zinc gluconate)**

Zinc is a constituent of many enzymes and is, therefore, essential to the body. It is present with insulin in the pancreas. It plays a role in DNA synthesis and cell division. Reported effects of deficiency include delayed puberty and hypogonadal dwarfism.

### **Iodine (Potassium Iodide)**

Iodine is an essential constituent of the thyroid hormones.

### **Green Tea**

Green tea is a dietary supplement that may improve mental alertness, relieve digestive symptoms and headaches, and help with weight loss.

## 5.2 Pharmacokinetic properties

The pharmacokinetics of the active substances would not be different from those naturally derived by food orally.

The following account describes the absorption and fate of each of the active constituents of Dr. wenger

### Vitamin A

Except when liver function is impaired, Vitamin A is readily absorbed.  $\beta$ -carotene (as in Dr. wenger) is Provitamin A and is the biological precursor to Vitamin A. It is converted to Vitamin A (Retinol) in the liver; retinol is emulsified by bile salts and phospholipids and absorbed in a micellar form. Part is conjugated with glucuronic acid in the kidney and part is metabolised in the liver and kidney, leaving 30 to 50% of the dose for storage in the liver. It is bound to a globulin in the blood. Metabolites of Vitamin A are excreted in the faeces and the urine.

### Vitamin D

The metabolism of ergocalciferol is similar to that of cholecalciferol. Cholecalciferol is absorbed from the gastro-intestinal tract into the circulation. In the liver, it is hydroxylated to 25-hydroxycholecalciferol, is subject to entero-hepatic circulation and is further hydroxylated to 1,25-dihydroxycholecalciferol in the renal tubule cells. Vitamin D metabolites are bound to specific plasma proteins.

### Vitamin B<sub>1</sub> (Thiamine)

Thiamine is absorbed from the gastro-intestinal tract and is widely distributed to most body tissues. Amounts in excess of the body's requirements are not stored but excreted in the urine as unchanged thiamine or its metabolites.

### Vitamin B<sub>2</sub> (Riboflavine)

Riboflavine is absorbed from the gastro-intestinal tract and in the circulation is bound to plasma proteins. It is widely distributed. Little is stored and excess amounts are excreted in the urine. In the body riboflavine is converted to flavine mononucleotide (FMN) and then to flavine adenine dinucleotide (FAD).

### Vitamin B<sub>6</sub> (Pyridoxine)

Pyridoxine is absorbed from the gastro-intestinal tract and converted to the active pyridoxal phosphate which is bound to plasma proteins. It is excreted in the urine as 4-pyridoxic acid.

### Vitamin B<sub>12</sub> (Cyanocobalamin)

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B<sub>12</sub> showed it was quickly taken up by the intestinal mucosa and held there for 2 - 3 hours. Peak concentrations in the blood and tissues did not occur until 8 - 12 hours after dosage with maximum concentrations in the liver within 24 hours. Cobalamins are stored in the liver, excreted in

the bile and undergo enterohepatic recycling. Part of a dose is excreted in the urine, most of it in the first eight hours.

### **Vitamin E**

Vitamin E is absorbed from the gastro-intestinal tract. Most appears in the lymph and is then widely distributed to all tissues. Most of a dose is slowly excreted in the bile and the remainder is eliminated in the urine as glucuronides of tocopheronic acid or other metabolites.

### **Nicotinamide (Nicotinic Acid Amide)**

Nicotinic acid is absorbed from the gastro-intestinal tract, is widely distributed in the body tissues and has a short half-life.

### **Calcium Pantothenate**

Pantothenic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. About 70% of pantothenic acid is excreted unchanged in the urine and about 30% in the faeces.

### **Vitamin H (d-Biotin)**

Following absorption, biotin is stored in the liver, kidney and pancreas.

### **Selenium**

Although it has been established that selenium is essential to human life, very little information is available on its function and metabolism.

### **Ferric Ammonium citrate (Iron)**

Iron is absorbed chiefly in the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach and if the iron is in the ferrous state as in ferrous fumarate. In conditions of iron deficiency, absorption is increased and, conversely, it is decreased in iron overload. Iron is stored as ferritin.

### **Magnesium glycinate (Magnesium)**

Magnesium salts are poorly absorbed from the gastro-intestinal tract; however, sufficient magnesium will normally be absorbed to replace deficiency states. Magnesium is excreted in both the urine and the faeces but excretion is reduced in deficiency states.

### **Zinc gluconate (Zinc)**

Zinc is poorly absorbed from the gastro-intestinal tract. It is widely distributed throughout the body. It is excreted in the faeces with traces appearing in the urine.

### **Potassium Iodide (Iodine)**

Iodides are absorbed and stored in the thyroid gland as thyroglobulin. Iodides are excreted in the urine with smaller amounts appearing in the faeces, saliva and sweat.



### **5.3 Preclinical safety data**

Not applicable.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Methyl paraben  
Propyl paraben  
Sodium benzoate  
Sucrose  
Liquid glucose  
Sodium hydroxide  
Sodium saccharine  
Propylene glycol  
Colour caramel  
Orange flavour  
Peppermint flavour  
Purified water  
Ethanol

### **6.2 Incompatibilities**

No major incompatibilities are known.

### **6.3 Shelf life**

Unopened: 2 years.

### **6.4 Special precautions for storage**

Do not store above 30° C

### **6.5 Nature and contents of container**

200ml amber colour glass bottle capped with 25mm ropp cap, packed in an inner packed.

### **6.6 Special precautions for disposal and other handling**

Not applicable.

## **7. manufactured by**

**Daily sun pharmaceutical company limited**

Plot 3 & 4 Tomori industrial estate,

off Idriko road, Ota,

Ogun state Nigeria

**Distributed by:**

**Jessy pharmaceutical company limited**

13B Acme road, Ogbaegbe industrial estate ikeja lagos