1. Name of the medicinal product

Generic: Multivitamin

Brand Name: Archivite Syrup

2. Qualitative and quantitative composition

Each 10ml contains

Raw Material	**Std Qty**
Riboflavin Sodium	1.233kg
Nicotinamide	4.400kg
Vitamin B_1	1.050kg
Vitamin B_{12}	0.002kg
Vitamin C	22.000kg
Sodium Hydroxide BP	0.600kg
Vitamin A	0.004kg
Vitamin D	0.002kg
Methyl Hydroxyl Benzoate	2.000kg
Propyl Hydroxyl Benzoate	0.200kg
Sodium Edetate	1.000kg
Sodium Metabisulphite	2.000kg
Sodium C M C	5.000kg
Sucrose BP	600.000kg
Banana Flavour	1.250L
Orange Flavour	4.250L

3. Pharmaceutical

Form: A brownish

colored 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

4.2 Method of administration: Oral

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

4.3 Contraindications

Archivite Syrup 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 Archivite syrup 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 Archivite Syrup on the ability to operate an automobile or other heavy machinery.

4.8 Undesirable effects

Generally multivitamin and multiminerals 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: Archivite Syrup 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.

5.2 Pharmcokinetics

The following account summarizes 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 isomerized 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 gastro- intestinal 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_1 (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_2 (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_6 (Pyridoxine)

Pyridoxine, once absorbed, is rapidly converted to the co-enzyme's 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_{12} (Cyanocobalamin)

Vitamin B_{12} 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_{12} interferes with haemopoiesis and produces megaloblastic anaemia.

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.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1a. List of excipients

Raw Material	**Std Qty**
Riboflavin Sodium	1.233kg
Nicotinamide	4.400kg
Vitamin B_1	1.050kg
Vitamin B_{12}	0.002kg
Vitamin C	22.000kg
Sodium Hydroxide BP	0.600kg
Vitamin A	0.004kg
Vitamin D	0.002kg
Methyl Hydroxyl Benzoate	2.000kg
Propyl Hydroxyl Benzoate	0.200kg
Sodium Edetate	1.000kg
Sodium Metabisulphite	2.000kg
Sodium C M C	5.000kg
Sucrose BP	600.000kg
Banana Flavour	1.250L
Orange Flavour	4.250L

6.2 Incompatibilities

No major incompatibilities are known.

6.3 Shelf life

2 years.

6.4 d. Special precautions for storage Do

not store above 30° C

6.5 Nature and contents of container

100ml amber colour plastic bottle capped with ropp cap, packed in an inner packet.

6.6 Special precautions for disposal and other handling

Notapplicable.

7. Manufactured and Distributed by

ARCHY PHARMACEUTICALS NIGERIA LIMITED

30, Winfunke Street by Access Bank Junction

Off Ahmadiyya B/Stop, Lagos-Abeokuta |Expressway,

Ojokoro, Lagos, Nigeria.