

Legal Category

POM: Over The Counter

- **SmPC**

---

## 1. Name of the medicinal product

VITAKRIS SYRUP

## 2. Qualitative and quantitative composition

### Each 5 ml contains :

Vitamin A 1000 i.u  
Vitamin B1 1200mcg  
Vitamin B2 1200mcg  
Vitamin B6 500mcg  
Vitamin B12 3mcg  
Vitamin C 40 mg  
Vitamin D2 200 i.u  
Nicotinamide 10 mg

## 3. Pharmaceutical form

Liquid Syrup

## 4. Clinical particulars

### 4.1 Therapeutic indications

**VITAKRIS SYRUP** is used as a supplement in the treatment of conditions associated with deficiency of certain B-complex vitamins, such as severe infections, degenerative diseases, endocrine dysfunction, surgical procedures, injuries, burns, old age, beriberi, riboflavinosis or pellagra.

### Posology and method of administration

For oral use

Adults:

One tablespoonful (15 mL) to be taken twice daily or as directed by the physician.

Children:

One teaspoonful (5 mL) to be taken 2-3 times daily or as directed by the physician.

Not recommended for children below 1 year.

#### **4.2 Contraindications**

Hypersensitivity to any component of this formulation, in conditions of irreversible liver insufficiency and severe uremia when dialysis possibilities are lacking.

Multivitamin Syrup is contra-indicated in those with the rare inborn errors of metabolism like Maple Syrup Urine Disease.

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

VITAKRIS SYRUP should be used cautiously in severe hepatic diseases and acute renal impairment. Appropriate laboratory tests, especially those for the monitoring of liver functions and renal functions, should be performed periodically during the course of use of the product. Amino Acids & Multivitamin Syrup should be given with caution to very sick children due to the risk of inducing hyperphenylalaninemia.

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

-MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines. Antihistamines may have additive effects with alcohol and other CNS depressants, e.g. hypnotics, sedatives, tranquillisers and anti-anxiety agents. Drugs with anti-serotonin activity, such as cyproheptadine, may interfere with serotoninenhancinganti-depressants including selective serotonin re-uptake inhibitors (SSRI's). This Pyridoxine may increase the peripheral metabolism of levodopa, reducing therapeutic efficacy of the latter drug. Therefore, patients with Parkinson's disease who are receiving treatment with plain levodopa should not take vitamin B6 in doses which greatly exceed the daily requirement.

#### **4.5 Fertility, pregnancy and lactation**

The use of any drug in pregnancy or in women of child-bearing age requires that the potential benefit of the drug should be weighed against possible hazards to the embryo and fetus. It is not known whether VITAKRIS SYRUP is excreted in human milk, and because of the potential for serious adverse reactions in breast-feeding infants from VITAKRIS SYRUP', a decision should be made whether to discontinue breast-feeding or to discontinue the drug,taking into account the importance of the drug to the mother.

#### **4.6 Effects on ability to drive and use machines**

No effect on driving vehicles or operating machines.

#### **4.7 Undesirable effects**

Hypersensitivity reaction (such as rash) and other side-effects reported are similar to those

associated with nausea, vomiting, abdominal pain or discomfort, blackening of stools, diarrhoea and/or constipation, but the incidence of side-effects is less owing to the controlled release nature of the formulation. Isolated cases of injury to mouth and pharynx, oesophageal ulcer, haematemesis and ileus have been reported.

#### **4.8 Overdose Symptoms and signs**

No cases of overdosage due to Multivitamin Syrup therapy have been reported.

### **5. Pharmacological properties**

#### **5.1 Pharmacodynamic properties**

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.

Colecalciferol:

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.

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.

**Riboflavin:**

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

**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.

**B-complex Vitamin** The vitamin B-complex comprises a group of water-soluble factors more or less closely associated in their natural occurrence. It is known that nearly every vitamin of the B-complex forms part of a co-enzyme essential for the metabolism of protein, carbohydrate or fatty acid

**Cyanocobalamin:**

Vitamin B12 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 B12 interferes with haemopoiesis and produces megaloblastic anaemia.

**Ascorbic Acid:**

Vitamin C cannot be synthesised by man therefore a dietary source is necessary. It acts as a cofactor in numerous biological processes including the hydroxylation of proline to hydroxyproline. In deficiency, the formation of collagen is, therefore, impaired. Ascorbic acid is important in the hydroxylation of dopamine to noradrenaline and in hydroxylations occurring in steroid synthesis in the adrenals. It is a reducing agent in tyrosine metabolism and by acting as an electron donor in the conversion of folic acid to tetrahydrofolic acid is indirectly involved in the synthesis of purine and thymine. Vitamin C is also necessary for the incorporation of iron into ferritin. Vitamin C increases the phagocytic function of leucocytes; it possesses anti-inflammatory activity and it promotes wound healing. Deficiency can produce scurvy. Features include swollen inflamed gums, petechial haemorrhages and subcutaneous bruising. The deficiency of collagen leads to development of thin

watery ground substances in which blood vessels are insecurely fixed and readily ruptured. The supportive components of bone and cartilage are also deficient causing bones to fracture easily and teeth to become loose. Anaemia commonly occurs probably due to Vitamin C role in iron metabolism.

Nicotinamide:

The biochemical functions of nicotinamide as NAD and NADP (nicotinamide adeninedinucleotide 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.

## **5.2 Pharmacokinetic properties**

Vitamin A:

Except when liver function is impaired, Vitamin A is readily absorbed. 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.

Colecalciferol:

Colecalciferol 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.

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.

Riboflavin:

Riboflavin 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 riboflavin is converted to flavine mononucleotide (FMN) and then to flavine adenine dinucleotide (FAD).

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.

**Cyanocobalamin:**

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B12 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.

**Ascorbic Acid:**

Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine and this elimination is usually accompanied by a mild diuresis.

**Nicotinamide:**

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

### **5.3 Preclinical safety data**

None.

## **6. Pharmaceutical particulars**

### **6.1 List of excipients**

Sucrose, Glycerin, Citric acid (monohydrate), Sodium citrate, Methyl Paraben, Propyl Paraben, Edetate disodium (sodium EDTA), Calcium Pantothenate, Strawberry Flavor, Benzoic acid, Alcohol, Water Purified.

### **6.2 Incompatibilities**

There are no significant incompatibilities with the product.

### **6.3 Shelf life**

3 Years.

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

Store in a cool, dark and dry place, below 30°C.

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

100 ml amber PET Bottle provided with a measuring cup.

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

No special requirements for disposal.

**7. Marketing authorisation holder** Krishat Pharma Industries Limited KM 15, Lagos-Ibadan Expressway, Ibadan, Oyo State, NIGERIA.

Email: info@krishatpharma.com

**8. Marketing authorisation number(s)**

NA

**9. Date of first authorisation/renewal of the authorisation**

NA

**10. Date of revision of the text**

NA

## **Company contact details**

### **Address**

Krishat Pharma Industries Limited KM 15, Lagos-Ibadan Expressway, Ibadan, Oyo State,  
NIGERIA.

### **Medical Information e-mail**

Email: [info@krishatpharma.com](mailto:info@krishatpharma.com)