

## BIORAJ PHARMACEUTICALS LIMITED

**BRAND NAME:** KISIVITE MULTIVITAMIN  
DROPS

**GENERIC NAME:** Vitamin A..... 4000 iu  
Vitamin B1..... 1 mg  
Vitamin B2..... 0.4 mg  
VitaminB6..... 0.5 mg  
Vitamin C..... 25mg  
Vitamin D ..... 400 iu  
Nicotinamide..... 5 mg

### SUMMARY OF PRODUCT CHARACTERISTICS

#### 1. NAME OF THE MEDICINAL PRODUCT

Kisivite Multivitamin Drops

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Vitamin A..... 4000 iu

Vitamin B1..... 1 mg

Vitamin B2.....0.4 mg

Vitamin B6..... 0.5 mg

Vitamin C..... 25 mg

Vitamin D ..... 400 iu

Nicotinamide ..... 5 mg

#### 3. PHARMACEUTICAL FORM

Oral Solution.

A yellow viscous syrup.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

Kisivite Drop is formulated to provide the necessary vitamins required during rapid growth and development of babies and toddlers. The Vitamins aid enzymatic reactions needed in the body for the maintenance of normal metabolic functions. Indications include:

- Improvement in appetite and optimal utilization of food intake.
- Vitamin deficiency state resulting in decreased mental function.
- As dietary supplements resulting in improved immune state.
- Deficiency of any of the constituent vitamins.
- Antibiotic therapy.

##### 4.2 Posology and method of administration

**Infants under one year:** 0.3ml (approx. 5 drops) daily

**One year old infant:**0.6ml (approx. 10 drops) daily or as directed by the physician.

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**4.3 Contraindications**

Known sensitivity to any of the excipients

**4.4 Special warnings and precautions for use**

Most vitamins are comparatively non-toxic but prolonged administration of high doses of vitamin A, Vitamin D and Vitamin B6 may have severe adverse effects. Side effects may include nausea, diarrhea or constipation.

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

The pyridoxine hydrochloride in Kisivite multivitamin may reduce the effectiveness of levodopa.

**4.6 Pregnancy and lactation**

Kisivite multivitamin is considered safe in the recommended dose.

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

None stated

**4.8 Undesirable effects**

None known

**4.9 Overdose**

Not applicable.

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#### 5. PHARMACOLOGICAL PROPERTIES

##### 5.1 Pharmacodynamic properties

***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.

***Ascorbic acid (Vitamin C):*** takes part in biochemical reactions involving oxidation, as in collagen synthesis, and in conversion of folic acid to folinic acid. It is also necessary for normal phagocytic function of WBCs (white blood cells).

Thus an adequate supply of these water-soluble vitamins is required for the optimum function of various cells and tissues.

These water soluble vitamins are not stored in the body to any significant extent, the excess quantities being excreted in the urine. Therefore, a regular and adequate intake of them is necessary to meet the metabolic requirements.

Deficiencies of water soluble vitamins often co-exist several of them because of their overlapping dietary sources and metabolic interdependence.

Initially the deficiency of these vitamins may be subclinical and demonstrable only by means of biochemical tests. If not corrected at this stage, it may become manifest as various symptoms, including impaired wound healing and increased susceptibility to infection.

Classical deficiency diseases such as beriberi, pellagra and scurvy are rare, whereas mild and subclinical deficiencies are probably more common, even among apparently healthy individuals.

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#### 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

Sodium CMC  
Sodium Ascorbate  
Sodium citrate  
Sorbitol  
Sodium methyl Paraben  
Sucrose  
Sodium Benzoate  
Citric Acid  
Propylene glycol  
Ethanol 96%  
Tween 80  
Sorbitol  
Pineapple flavor

#### 6.2 Incompatibilities

None known

#### 6.3 Shelf life

24 months.

#### 6.4 Special precautions for storage

Keep in a cool dry place below 30°C away from light.Keep out of reach of children.

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**6.5 Nature and contents of container**

15ml amber plastic bottle in a cardboard carton along with packing leaflet

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

None stated

**7. MARKETING AUTHORISATION HOLDER**

*Bioraj Pharmaceuticals Limited*  
*No 405 Kaiama Road, Ilorin*  
*biorajpharmaceuticalltd@gmail.com*