

BIORAJ PHARMACEUTICALS LIMITED

BRAND NAME: Dr. Kisi's Vitamin B-complex

GENERIC NAME: Vitamin B1..... 5 mg
Vitamin B2.....2 mg
Vitamin B6..... 2 mg
Nicotinamide 20 mg

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dr. Kisi's Vitamin B-complex

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Vitamin B1..... 5 mg
Vitamin B2.....2 mg
Vitamin B6..... 2 mg
Nicotinamide 20 mg

3. PHARMACEUTICAL FORM

Oral Solution.

A yellow viscous syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Dr. Kisi's Vitamin B-complex syrup is a preparation of multivitamins which are present in sufficient amount to prevent deficiencies of the contained vitamins and promote healthy growth.

Indications include:

- a) Improvement of appetite and optimal utilization of food intake.
- b) Vitamin B1 deficiency resulting in Beriberi, Vitamin B2 deficiency resulting in angular stomatitis, vascularized cornea, photophobia and a burning sensation of the eye; neuritis in adult. In children, vitamin B6 deficiency affects the central nervous system adversely.
- c) Deficiency of Nicotinamide leading to Pellagra, loss of appetite, lethargy, mental and neurological disturbance.

As dietary supplements resulting in a compromised immune state.

4.2 Posology and method of administration

Children: 2.5-5ml daily.

Adult and children above 10 years: 5-10ml daily or as directed by the physician.

4.3 Contraindications

Known sensitivity to any of the excipients

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4.4 Special warnings and precautions for use

Most vitamins are comparatively non-toxic but prolonged administration of high doses of 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 Dr Kisi's Vitamin B-complex may reduce the effectiveness of levodopa.

4.6 Pregnancy and lactation

Dr Kisi's Vitamin B-complex 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.

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 beri beri, pellagra and scurvy are rare, whereas mild and subclinical deficiencies are probably more common, even among apparently healthy individuals.

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

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium CMC
Sodium methyl Paraben
Sucrose
Sodium citrate
Sodium Benzoate
Citric Acid
Propylene glycol
Ethanol 96%
Banana 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.

6.5 Nature and contents of container

100ml 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
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