

Legal Category
POM: Prescription only medicine

- **SmPC**
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1. Name of the medicinal product

KRISHAT B COMPLEX SYRUP

2. Qualitative and quantitative composition

Each 5 ml solution contains

Vitamin B1 1200mcg

Vitamin B2 1200mcg

Vitamin B6 500mcg

Nicotinamide 10 mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Liquid Syrup

4. Clinical particulars

4.1 Therapeutic indications

Oral prophylactic and therapeutic treatment of vitamin B complex deficiency.

4.2 Posology and method of administration

Prophylactic

Children

up to 1 year, One 5ml spoonful daily

up to 12 years, One 5ml spoonful twice daily

Adults and elderly

One 5ml spoonful three times daily

Therapeutic

Children

up to 1 year, One 5ml spoonful three times daily

up to 12 years, Two 5ml spoonfuls three times daily

Adults and elderly

Two to three 5ml spoonfuls three times daily

Or as prescribed by a doctor

4.3 Contraindications

Known sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

No special warnings.

4.5 Interaction with other medicinal products and other forms of interaction

The pyridoxine hydrochloride may reduce the effectiveness of levodopa.

4.6 Fertility, pregnancy and lactation

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

5. Pharmacological properties

5.1 Pharmacodynamic properties

Vitamin B Complex.

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.

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.

6. Pharmaceutical particulars

6.1 List of excipients

Sucrose BP
Sodium Saccharin BP
Sodium Citrate BP
Citric Acid BP
Sodium methyl paraben BP
Sodium propyl paraben BP
Colour amaranth
Levomenthol BP
Propylene Glycol BP
Flavour Raspberry
Distilled water

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 dry place in the original package.

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**

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