1. NAME OF THE MEDICINAL PRODUCT

KRISHAT B-COMPLEX TABLET

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sugar coated tablets contains:

Vitamin B1.……1.0 mg

Vitamin B2-……1.0 mg

Vitamin B6..……1.0 mg

Niacinamide.……15.0 mg

Excipients …….q.s.

Excipients with known effect:

Maize Starch, Dibasic Calcium Phosphate Microcrystalline Cellulose, Sodium Starch Glycolate, P.V.P.K 90, Sodium Methyl Paraben, Sodium Propyl Paraben, Magnesium Stearate, Purified Talc, Colloidal Silicon Dioxide (Aerosil), Sodium Benzoate, butyl Hydroxyl Toluene, butyl Hydroxyl Anisole, Cross Carmelose Sodium, Iso-Propyl Alcohol, Di Sodium E.D.T.A , Calcium Carbonate , Sucrose , Gelatin , Carbon Tetrachloride , Quinoline yellow, Beeswax, Carnauba Wax, Ethyl cellulose, Iron Oxide Yellow

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet

Yellow color sugar coated tablets, plain on both side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of clinical and sub-clinical vitamin B deficiency states (manifestations of which include glossitis, stomatitis, cheilosis, the heart manifestations of beriberi, the skin manifestations of pellagra, corneal vascularisation and polyneuritis).

4.2 Posology and method of administration

Posology

Adults (including elderly) and children over 3 years: One to two tablets three times daily.

Paediatric population: Should not be used in children under 3 years.

Method of administration

Tablet for oral administration

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

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. This does not apply when levodopa is combined with a peripheral decarboxylase inhibitor.

4.6 Pregnancy, Lactation & Fertility

Pregnancy

There is limited amount of data from the use of the product in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. The use of the product is individualized based on condition and requirements in pregnant women and can be used in pregnant women if use is necessary to correct deficiencies and if benefits overweighs risks.

Caution should be exercised when prescribing to pregnant women

Breast-feeding:

The ingredients of Vitamin B compound tablets are excreted via human milk. No harm to suckling infant is expected if used in recommended doses. High concentrations of vitamin B6 can inhibit the production of breast milk. However, the use should be individualized based on nutritional status of the lactating women and infant. The diet and use of any additional B vitamin supplements in both mother and infant should be reassessed so that neither excess nor lesser B vitamins available to lactating women and infant.

In high doses, pyridoxine may interfere with prolactin release and should only be used with caution in nursing mothers.

Fertility: No relevant data is available

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Vitamin B Compound Strong tablets are unlikely to cause any side effects, as any excess vitamin B is naturally excreted from the body.

Seek medical attention right away if any of these SEVERE side effects like severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); feeling of swelling of the entire body; numbness or tingling of the skin occur while taking Vitamin B Compound Strong)

Reporting of suspected adverse reactions

4.9 Overdose

Excess vitamin B is readily excreted, therefore no serious problems are anticipated for the administration of vitamin B in this form.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Nicotinamide is a vitamin (B3)

Pyridoxine hydrochloride is a vitamin (B6)

Riboflavine is a vitamin (B2)

Thiamine mononitrate is a vitamin (B1)

The ATC code of Vitamin B complex is A11EA. 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.

5.2 Pharmacokinetic properties

Nicotinamide is readily absorbed from the GI tract following oral administration and is widely distributed in the body tissues. Small amounts of nicotinamide are excreted unchanged in urine following therapeutic doses, however, the amount excreted unchanged is increased with larger doses.

Pyridoxine is absorbed from the GI tract and is converted to the active form pyridoxal phosphate. It is excreted in the urine as 4-pyridoxic acid.

Riboflavine is absorbed from the GI tract and in the circulation is bound to plasma proteins. Although widely distributed, little is stored in the body, and amounts in excess of requirements are excreted in the urine.

Thiamine is absorbed from the GI tract and is widely distributed to most body tissues. It is not stored to any appreciable extent in the body and amounts in excess of requirements are excreted in the urine as unchanged thiamine or metabolites

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch, Dibasic Calcium Phosphate Microcrystalline Cellulose, Sodium Starch Glycolate, P.V.P.K 90, Sodium Methyl Paraben, Sodium Propyl Paraben, Magnesium Stearate, Purified Talc, Colloidal Silicon Dioxide (Aerosil), Sodium Benzoate, butyl Hydroxyl Toluene, butyl Hydroxyl Anisole, Cross Carmelose Sodium, Iso-Propyl Alcohol, Di Sodium E.D.T.A, Calcium Carbonate, Sucrose , Gelatin , Carbon Tetrachloride , Quinoline yellow, Beeswax, Carnauba Wax, Ethyl cellulose & Iron Oxide Yellow.

6.2 Incompatibilities

Not Known

6.3 Shelf-life

Blisters: 36 Months

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

The tablets are packed in Alu/PVC blister and inserted in a mono carton. Pack sizes: 3x10 Tablets

6.6 Special precautions for disposal and other handling

No special requirements

7.0 Manufactured by:

Krishat Pharma Industries Limited
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NIGERIA.
Email: info@krishatpharma.com

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