For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

B-COMPLEX FORTE WITH VITAMIN C CAPSULES

BECOSULES® Capsules

1. NAME OF THE MEDICINAL PRODUCT

BECOSULES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Thiamine Mononitrate I.P.	10 mg
Riboflavin I.P.	10 mg
Pyridoxine Hydrochloride I.P.	3 mg
Vitamin B12 I.P. (as STABLETS 1:100)	15 mcg
Niacinamide I.P.	100 mg
Calcium Pantothenate I.P.	50 mg
Folic Acid I.P.	1.5 mg
Biotin U.S.P.	100 mcg
Ascorbic Acid I.P. (as coated)	150 mg

Appropriate overages added

For Therapeutic Use

For a full list of excipients, see section 6.1.
All strengths/presentations mentioned in this document might not be available in the market.

3. PHARMACOLOGICAL FORM

Capsules

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

®Trademark Proprietor: Pfizer Products Inc. USA
Licensed User: Pfizer Limited, India

Becosules capsules are indicated in the treatment of patients with deficiencies of, or increased requirement for, vitamin B-complex, and vitamin C. Such patients and conditions include:

- Decreased intake because of restricted or unbalanced diet as in anorexia, diabetes mellitus, obesity and alcoholism.
- Reduced availability during treatment with antimicrobials which alter normal intestinal flora, in prolonged diarrhea and in chronic gastro-intestinal disorders.
- Increased requirements due to increased metabolic rate as in fever and tissue wasting, e.g. febrile illness, acute or chronic infections, surgery, burns and fractures.
- Stomatitis, glossitis, cheilosis, paraesthesias, neuralgia and dermatitis.
- Micronutrient deficiencies during pregnancy or lactation.

4.2 Posology and Method of Administration

One capsule daily, or as directed by the physician.

4.3 Contraindications

Hypersensitivity to any of the ingredients of Becosules capsules.

4.4 Special Warnings and Precautions for Use

The use of Becosules capsules in patients with deficiency or increased requirement of vitamins B-complex, and vitamin C should be accompanied by specific therapy for the primary illness. Treatment with Becosules capsules should be continued only until the deficiency is corrected or the need for supplementation exists.

Pyridoxine in Becosules capsules may reduce the therapeutic effects of levodopa in Parkinson's disease.

Riboflavin in Becosules capsules may color the urine yellow.

During treatment with Becosules capsules, the urine may give a false positive result for sugar by Benedict's test because of the presence of ascorbic acid. Therefore, a test not affected by ascorbic acid, should be used.

In pernicious anemia, folic acid in Becosules capsules may correct anemia but aggravate neurological lesion.

4.5 Interactions with other medications

Although the clinical importance is unknown, thiamine reportedly may enhance the effect of neuromuscular blocking agents. The rate and extent of absorption of riboflavin are reportedly affected by propantheline bromide.

Pyridoxine hydrochloride reverses the therapeutic effects of levodopa by accelerating peripheral metabolism of levodopa.

Absorption of vitamin B_{12} from the GI tract may be decreased by aminoglycoside antibiotics, colchicine, extended-release potassium preparations, aminosalicylic acid and its salts and anticonvulsants (e.g., phenytoin, phenobarbital, primidone).

Prednisone has been reported to increase the absorption of vitamin B_{12} in a few patients with pernicious anemia. The clinical importance of these findings is unknown. Concurrent administration of chloramphenicol and vitamin B_{12} reportedly may antagonize the hematopoietic response to vitamin B_{12} in vitamin B_{12} deficient patients. The hematologic response to vitamin B_{12} in patients receiving both drugs should be carefully monitored and alternate anti-infectives should be considered. Niacin reportedly potentiates the hypotensive effect of ganglionic blocking drugs.

4.6 Pregnancy and Lactation

In pregnant and lactating women, dosing should be per recommended allowances for their condition as advised by physician, since their vitamin requirements may be higher.

4.7 Effects on ability to drive and use machines

The medication does not have any effect on ability to drive and use machines.

4.8 Undesirable Effects

Hypersensitivity reactions have been reported with thiamine and folic acid, although these are rare.

4.9 Overdose

B-complex vitamins are water soluble and excess vitamins are expelled in urine. Hence overdose is very rare.

5. PHARMACOLOGICAL PROPERTIES[1-7]

B-Complex vitamins, and vitamin C, function as cofactors of various enzymes which regulate carbohydrate, protein and fat metabolism.

Thiamine

Thiamine (B_1) acts as a cofactor in the decarboxylation of keto acids such as pyruvic acid. Thiamine is readily absorbed from the upper GI tract following oral administration. It is widely distributed into body tissues. Several urinary metabolites of thiamine have been identified in humans.

Riboflavin (B_2)

Riboflavin (B_2) plays a vital role in cellular respiratory reactions in conjunction with niacinamide. Riboflavin is readily absorbed from the upper GI tract. Riboflavin is stored in limited amounts in the liver, spleen, kidneys, and heart, mainly in the form of Flavidine Adenine Dinucleotide. Following ingestion of usual physiologic doses of riboflavin, only about 9% of the drug is excreted in urine unchanged. The fate of the remainder of the drug is unknown.

Pyridoxine (B_6)

Pyridoxine (B_6) takes part in decarboxylation and interconversion of amino acids. It is also required for normal antibody-mediated and cell-mediated immune responses.

Pyridoxine is readily absorbed from the GI tract following oral administration. Vitamin B_6 is stored mainly in the liver with lesser amounts in muscle and brain. The biologic half-life of pyridoxine appears to be 15–20 days.

Ascorbic acid (Vitamin C)

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). Ascorbic acid is readily absorbed after oral administration; however, absorption involves an active process and may be limited after very large doses. Ascorbic acid is widely distributed in body tissues. Large concentrations of the vitamin are found in the liver, leukocytes, platelets, glandular tissues, and the lens of the eye. About 25% of the ascorbic acid in plasma is bound to proteins. When the body is saturated with ascorbic acid and blood concentrations exceed the threshold, unchanged ascorbic acid is excreted in the urine.

Vitamin B_{12} (Cyanocobalamin)

Vitamin B_{12} is irregularly absorbed from the distal small intestine following oral administration. Absorption of vitamin B_{12} following oral administration is decreased by structural or functional damage to the stomach or ileum. Vitamin B_{12} is distributed into the liver, bone marrow, and other tissues, including the placenta. Vitamin B_{12} is believed to be converted to coenzyme form in the liver and is probably stored in tissues in this form. The major portion of vitamin B_{12} is excreted within the first 24 hours.

Niacinamide

Niacinamide (nicotinamide) plays a vital role in cellular respiration in conjunction with riboflavin. Niacinamide are readily absorbed from the GI tract following oral administration. Niacinamide is widely distributed into body tissues. Following administration of physiologic doses of niacin or niacinamide, only a small amount of niacinamide is excreted unchanged in urine; however, following administration of larger doses, a greater proportion of niacin and niacinamide is excreted unchanged.

Calcium Pantothenate

Calcium pantothenate functions as a cofactor for enzymes involved in transfer of acetyl groups. It is also required for normal antibody response in conjunction with pyridoxine. Pantothenic acid is readily absorbed from the GI tract following oral administration. Highest concentrations are found in the liver, adrenal glands, heart, and kidneys. About 70% of an oral dose of pantothenic acid is excreted unchanged in urine and about 30% in feces.

Folic acid

Folic acid, after conversion in the body to folinic acid, takes part in reactions involved in the synthesis of nucleotides and maturation of RBCs in conjunction with vitamin B12. It also plays an important role in lymphocyte-mediated immune response. Folic acid is absorbed rapidly from the GI tract following oral administration. Larger doses of folic acid may escape metabolism by the liver and appear in the blood mainly as folic acid.

Biotin

Biotin is a sulfur-containing, water-soluble vitamin. In humans, the essential requirement for biotin arises from its obligatory involvement in carbohydrate, lipid and protein metabolism. It is an integral part of enzymes that play essential roles in gluconeogenesis, fatty acid synthesis, and metabolism of branched-chain amino acids.

Thus an adequate supply of these micronutrients is required for the optimum function of various cells and tissues.

Except for vitamin B_{12}, the water-soluble vitamins are not stored in the body to any significant extent, the excess quantities being excreted in the urine. The body pool of readily available zinc too appears to be small and to have a rapid turnover rate. Therefore, a regular and adequate intake of these micronutrients is necessary to meet the metabolic requirements. Deficiencies of water-soluble vitamins often co-exist because of their overlapping dietary sources and metabolic interdependence. Marginal states of zinc nutrition also occur under similar circumstances. Initially the deficiency of these micronutrients 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, scurvy, and zinc deficient hypogonadism and dwarfism are rare, whereas mild and subclinical deficiencies are probably more common, even among apparently healthy individuals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Tribasic Calcium Phosphate, Light liquid Paraffin, Magnesium Stearate, Maize Starch and Talcum. Colors used in hard gelatin capsule shell: Brilliant Blue FCF, Ponceau 4R and Sunset yellow FCF

6.2 Incompatibilities

None specific

6.3 Shelf-Life

18 Months

6.4 Special Precautions for Storage

Store below 25°C, in a dry place.

6.5 Nature and Contents of Container

Aluminium strips of 20 capsules, 25 strips in a carton.

6.6 Instructions for Handling

None specific.

The reference for the text of the document has been mentioned below:

1. Marcus R, Goulston AM. In: Gilman AG, Goodman LS, Rall TW, Murad F, eds. The Pharmocological Basis of Therapeutics. 7th ed. New York: Macmillan; 1985. p.1544-52.

2. Biesel WR. Single nutrients and immunity. Am J Clin Nutr. 1982; 35 (Suppl): 417-68.

3. Gillman RS. In: Gilman AG, Goodman LS, Rall TW, Murad F, eds. The Pharmacological Basis of Therapeutics. 7th ed. New York: Macmillan; 1985. p.1323-24.

4. Food and Nutrition Board, Commission of Life Sciences, National Research Council. Water-Soluble Vitamins. Biotin In: Recommended Dietary Allowances. 10th ed. Washington, DC: National Academy Press; 1989. p. 165-69.

5. Bamji MS. Biochemical assessment of vitamin nutritional status and interrelationship between vitamins. Indian J Med Res. 1975; 63:444-56.

6. Bianchine JR. In: Gilman AG, Goodman LS, Rall TW, Murad F, eds. The Pharmacological Basis of Therapeutics. 7th ed. New York: Macmillan; 1985.p. 479-80.

7. Bradley GM, Benson ES. In: Davidson I, Henry JB, eds. Clinical Diagnosis by Laboratory Methods. 15th ed. Delhi: Macmillan; 1977. p. 56.