

BECOSULES[®] CAPSULES SUMMARY OF PRESCRIBING INFORMATION

Before prescribing, please refer to the full prescribing information of Becosules[®] Capsules

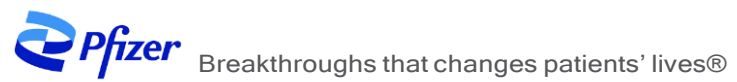
[Becosules][®] Capsules Abbreviated Prescribing Information / Summary of Product Information

GENERIC NAME: B-Complex Forte with Vitamin C Capsules. **PRESENTATION:** Each hard gelatin 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, Excipients q.s. Appropriate overages added. *Dosage form:* Hard Gelatin Capsules, *Pack size-* Aluminium strips of 20 capsules, 25 strips in a carton. **INDICATION(s):** 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. **DOSAGE AND ADMINISTRATION:** One capsule daily, or as directed by the physician. 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.

CONTRAINDICATIONS: Hypersensitivity to any of the ingredients of Becosules capsules. **WARNING AND PRECAUTIONS:** 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. **DRUG INTERACTIONS:** 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 B12 from the GI tract may be decreased by aminoglycoside antibiotics, colchicine, extended-release potassium preparations, aminosalicic acid and its salts and anticonvulsants (e.g., phenytoin, phenobarbital, primidone). Prednisone has been reported to increase the absorption of vitamin B12 in a few patients with pernicious anemia. The clinical importance of these findings is unknown. Concurrent administration of chloramphenicol and vitamin B12 reportedly may antagonize the hematopoietic response to vitamin B12 in vitamin B12 deficient patients. The hematologic response to vitamin B12 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. **OVERDOSE:** B-complex vitamins are water soluble and excess vitamins are expelled in urine. Hence overdose is very rare. **ADVERSE REACTION:** Hypersensitivity reactions have been reported with thiamine and folic acid, although these are rare. **PHARMACEUTICAL PRECAUTIONS:** *Shelf life:* 18 Months. *Storage:* Store below 25°C, in a dry place. **REFERENCE:** Version LPDBCC092021 Dated September 2021. **DATE OF THIS DOCUMENT:** February 3rd, 2022.

Becosules[®] capsules Trademark Proprietor: Pfizer Products Inc. USA. Licensed User: Pfizer Limited, India

Full product information available on request.



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