**For the use of Registered Medical Practitioners or a Hospital or a Laboratory.**

# B-Complex with Vitamin C Syrup
# BECOSULES® SYRUP

## 1. NAME OF THE MEDICINAL PRODUCT

BECOSULES Syrup

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml (one teaspoonful) contains:

| | |
|---|---|
| Thiamine Hydrochloride I.P. | 2.00 mg |
| Riboflavin Sodium Phosphate I.P. | 2.54 mg |
| Pyridoxine Hydrochloride I.P. | 2.00 mg |
| Niacinamide I.P. | 20.00 mg |
| D-Panthenol I.P. | 6.00 mg |
| Ascorbic Acid I.P. | 75 mg |

In a flavored Syrupy base
Appropriate overages added
For Full list of excipients refer section 6.1

All strengths/presentations mentioned in this document might not be available in the market.

## 3. PHARMACOLOGICAL FORM

Syrup

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Becosules syrup is indicated in the treatment of patients (1 year or older) with deficiencies of, or increased requirement for, vitamin B Complex and C. Such patients and conditions include:

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- Decreased intake because of restricted or unbalanced diet as in anorexia, diabetes mellitus, obesity
- Reduced availability during treatment with antimicrobials which alter normal intestinal flora, in prolonged diarrhea and in chronic gastrointestinal disorders.
- Increased requirements due to increased metabolic rate as in fever and tissue wasting,[1] e.g. febrile illness, acute or chronic infections, surgery, burns and fractures
- Stomatitis, glossitis, cheilosis, paraesthesias, neuralgia and dermatitis

## 4.2 Posology and Method of administration

For Children above 1 year: one teaspoonful (5 ml) daily, or as advised by the physician.

## 4.3 Contraindications

Hypersensitivity to any of the ingredients of Becosules syrup.

## 4.4 Special Warnings and Precautions for Use

The use of Becosules syrup in patients with deficiency or increased requirement of vitamins B-complex and C should be accompanied by specific therapy for the primary illness.

Treatment with Becosules syrup should be continued only until the deficiency is corrected or the need for supplementation exists.

Pyridoxine in Becosules syrup may reduce the therapeutic effect of levodopa in Parkinson's disease.[4]

Riboflavin in Becosules syrup may color the urine yellow.

During treatment with Becosules syrup the urine may give a false positive result for sugar by Benedict's test because of the presence of ascorbic acid.[5] Therefore, a test not affected by ascorbic acid should be used.

Keep out of reach of children.
Do not exceed recommended daily dose/amount

## 4.5 Interactions with other medications

Although the clinical importance is unknown, thiamine reportedly may enhance the effect of neuromuscular blocking agents.

Niacin reportedly potentiates the hypotensive effect of ganglionic blocking drugs.

## 4.6 Pregnancy and lactation

As with any other drug, if you are a pregnant or nursing baby, contact your healthcare professional before taking this drug.

## 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 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.

In case of accidental overdose, discontinue use and seek professional assistance immediately.

# 5. PHARMACOLOGICAL PROPERTIES

B Complex vitamins and vitamin C function as cofactors of various enzymes which regulate carbohydrate, protein and fat metabolism.[1]

Thiamine ($B_1$) acts as a cofactor in the decarboxylation of keto acids such as pyruvic acid.

Riboflavin ($B_2$) plays a vital role in cellular respiratory reactions in conjunction with niacinamide.

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.[2]

Niacinamide (nicotinamide) plays a vital role in cellular respiration in conjunction with riboflavin

D-Panthenol functions as a cofactor for enzymes involved in transfer of acetyl groups. It is also required for normal antibody response in conjunction with pyridoxine.

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).[2]

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.[1]

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[-3]

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of Excipients

Sodium Benzoate I.P., Disodium Edetate I.P., Citric acid Monohydrate I.P., Sodium Carbonate (anhydrous) I.P., Raspberry Flavor, Purified water I.P., Sucrose I.P. and Sorbitol Solution 70 % (Non- crystallizing) I.P. Nitrogen # and Hyflo Supercel [#],

[#] Hyflo Supercel (used as filter aid), and Nitrogen (used as inert atmosphere), # Nitrogen is used to replace the air from filled bottles.

### 6.2 Incompatibilities

None specific

### 6.3 Shelf-Life

12 Months

### 6.4 Special Precautions for Storage

- Store below 25° C. Replace cap securely.

### 6.5 Nature and Contents of Container

60 ml and 120 ml in Amber coloured glass bottles.

### 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 Pharmacological Basis of Therapeutics*, 7th ed. New York: Macmillan, 1985:1544-52.

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

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

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

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