

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Becovit Syrup® (Vitamin B Complex)

Strength

Each 5 ml (one teaspoonful) contains:

Vitamin B1 (Thiamine Hydrochloride)	5mg
Vitamin B2 (Riboflavin).....	2mg
Vitamin B6 (Pyridoxine Hydrochloride)	2mg
Nicotinamide.....	20mg

Pharmaceutical/Dosage form

Syrup.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml (one teaspoonful) contains:

Vitamin B1 (Thiamine Hydrochloride)	5mg
Vitamin B2 (Riboflavin).....	2mg
Vitamin B6 (Pyridoxine Hydrochloride)	2mg
Nicotinamide.....	20mg

Excipients:

For Full list of excipients refer section 6.1

3. PHARMACEUTICAL FORM

Syrup

A clear yellow viscous syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Becovit syrup is indicated for:

- Prophylactic or therapeutic nutritional supplement of the B-complex vitamins in cases of inadequate dietary intake.
- Nutritional supplementation to prevent vitamin B deficiencies in situations of increased vitamin B requirements such as in breast feeding, growing children, pregnancy, infections, convalescence, diminished appetite, anorexia.
- Adjunct treatment of various conditions of physiological stress such as diarrhea, vomiting, severe burns, recovery from surgery.
- Therapeutic nutritional supplement in the following conditions of vitamin B complex deficiencies manifestation: neuritis, neuralgia, sciatica, post infectious polyneuritis, diabetic polyneuropathy, central spastic conditions; myasthenia; paresthesia, dermatitis, neurodermatitis, asthenia and other conditions as may be determined by physician.

4.2 Posology and Method of administration

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

Adult: one teaspoonful (5 ml) two times daily

4.3 Contraindications

Becovit syrup should not be used in cases of hypersensitivity to any of the vitamins.

4.4 Special Warnings and Precautions for Use

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

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

Pyridoxine in Becovit syrup may reduce the therapeutic effect of levodopa in Parkinson's disease.

Riboflavin in Becovit syrup may color the urine yellow.

During treatment with Becovit syrup 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.

Keep out of reach of children.

Do not exceed recommended daily dose/amount

4.5 Interactions with other medications

Although 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 the 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

Thiamine (B₁) acts as a cofactor in the decarboxylation of keto acids such as pyruvic acid. Riboflavin (B₂) plays a vital role in cellular respiratory reactions in conjunction with niacinamide. Pyridoxine (B₆) takes part in decarboxylation and interconversion of amino acids. It is also required for normal antibody mediated and cell mediated immune responses.

Nicotinamide plays a vital role in cellular respiration in conjunction with Riboflavin.

6. PHARMACEUTICAL PARTICULARS**6.1 List of Excipients**

S.NO	Composition	Reference
1.	Thiamine Hydrochloride (Vitamin. B1)	BP
1.	Thiamine Hydrochloride	
2.	Riboflavin -5- Phosphate Sodium (Vitamin B2)	BP
3.	Pyridoxine Hydrochloride (Vitamin. B6)	BP
4.	Nicotinamide	BP
5.	Glycerin	BP
6.	Sugar	BP
7.	Liquid Sorbitol	BP
8.	Methyl Paraben	BP
9.	Propyl Paraben	BP
10.	Orange Flavour	IHS
11.	FD & C Yellow	IHS
12	Purified Water (to)	BP

6.2 Incompatibilities

Nonspecific

6.3 Shelf-Life

24 Months

6.4 Special Precautions for Storage

Store below 30°C, in a dry place. Protect from light.

Keep all medicine away from the reach of children.

6.5 Nature and Contents of Container

100 ml in Amber colored Pet bottle.

7. APPLICANT/HOLDER OF CERTIFICATE PRODUCT REGISTRATION.

Unique Pharmaceuticals Limited
11, Fatai Atere Way, Matori-Mushin Lagos
Tel: +234 8097421000
Email: mail@uniquepharm.com

8. DRUG PRODUCT MANUFACTURER

Unique Pharmaceuticals Limited
Km 38, Abeokuta Road, Sango-Ota,
Ogun State, Nigeria.
Tel: +234 8097421000
Email: mail@uniquepharm.com

9. NAFDAC REGISTRATION NUMBER(S)

A11-0793

10. DATE OF REVISION OF THE TEXT

20/12/2028