BCOSAM TABLETS

Thiamine Hcl (Vitamin B1), Riboflavin (Vitamin B2), & Nicotinamide

Summary of Product Characteristics

Document type:	Summary of Product Characteristics
Document status:	Final
Release date:	17th August 2020
Number of pages:	5 pages

1. NAME OF THE MEDICINAL PRODUCT

BCOSAM TABLETS 1MG/1MG/15MG

2. QUALITATIVE AND QUANTITATIVE COMPOSITIONS

Each tablet contains:

Thiamine Hcl (Vitamin B1)	B.P	1mg
Riboflavin (Vitamin B2)	B.P	1mg
Nicotinamide	B.P	15mg
Excipients……..……..		q.s.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORMS

Yellow flat bevelled tablets with 'BCO' marked one side and plain on the other side.
Oral Tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication.

Indicated for deficiencies in Vitamins and as dietary supplement.

4.2 Posology and method of administration.

Tablet: One tablet to be taken two or three times a day after food.

4.3 Contraindications

There is no known contraindication to the use of Vitamins.

4.4 Special warnings and precaution for use.

***Children*:**
Keep out of reach of children

***Teratogenicity*:**

There are no reported cases of Bcosam Tablets being teratogenic in scientific literature.

4.5 Interaction with other medicinal product and other forms of interaction.

There is no known interaction with other medicinal product and other forms of interaction to the use of BCOSAM TABLET.

4.6 Pregnancy and Lactation.

We do not have clinical studies that against the safety of BCOSAM TABLETS for use during pregnancy; we advise that you consult your physician.

4.7 Effect on the ability to drive and use machine.

Not applicable.

4.8 Undesirable effect.

There is no toxic effects are unlikely since any excess vitamin B is excreted.

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 Pharmacodynamic properties.

BCOSAM TABLETS which is 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 glycemic index 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

Riboflavine is absorbed from the glycemic index 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 glycemic index 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.

Product is not a new chemical entity therefore this section is not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Di-calcium phosphate

Maize starch

Purified Talcum

Magnesium stearate

Gelatine

Methyl paraben

Propyl paraben

6.2 Incompatibilities

Unknown

6.3 Shelf-life

24 Months from the date of manufacture

6.4 Special precautions for storage

Protect from heat and light and store in a cool dry place below 30^0C

6.5 Nature and composition of immediate packaging

Bulk pack tablet whose quality has been approved by the quality control department in polythene bags in 1000's by weight. Seal the bags and place them in previously cleaned 350cc plastic securi-containers.

7 MARKETING AUTHORISATION HOLDER

SAM PHARMACEUTICALS LIMITED.
2, WESTERN RESERVOIR ROAD,
ILORIN,
KWARA STATE, NIGERIA.
08057075266
sampharmaceuticalltd@gmail.com

.

8 MARKETING AUTHORISATION NUMBER(S)

04 – 0268.

9 AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal date: 2nd June 2016

10 DATE OF REVISION OF THE TEXT

17th August 2025