PROFESSIONAL INFORMATION

Scheduling status: S0

D.34.11 Vitamins; Complementary Medicine: Health Supplement

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety and intended use.

1. NAME OF THE MEDICINE

GNC B COMPLEX CAPSULES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Thiamine (Vitamin B1)	50 mg
Riboflavine (Vitamin B2)	50 mg
Calcium D pantothenate (Vitamin B5)	50 mg
Pyridoxine (Vitamin B6)	50 mg
Inositol (Vitamin B8)	50 mg
Para-Amino Benzoic Acid (Vitamin B10)	50 mg
Nicotinic acid	35 mg
Choline Bitartrate	0.5 mg
Folic Acid	0.4 mg
Cyanocobalamine (Vitamin B12)	0.05 mg
Biotin	0.05 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules
Clear capsule containing a yellow powder.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

B COMPLEX CAPSULES are a general, daily vitamin supplement. It contains a combination of vitamins essential for energy production and to assists the body to metabolise carbohydrates, fats and proteins. B COMPLEX CAPSULES help maintain general good health.

4.2. Posology and method of administration

Posology
Adults:
Take one (1) capsule daily after a meal, or as prescribed. Do not exceed the recommended dosage.

Method of administration
This medicine is taken orally. The capsule should be swallowed with a glass of water.

4.3. Contraindications

- Known hypersensitivity to any of the ingredients.
- Patients with a bleeding disorder.
- Patients who suffer from disturbances of calcium metabolism e.g. hypercalcaemia

4.4. Special warnings and precautions for use

Take care in patients who:

- are taking blood thinning medication or other anti-coagulant medication. It might be necessary to increase monitoring of the INR (International Normalised Ratio) levels.
- have cobalt or cobalamin hypersensitivity as B COMPLEX CAPSULES contains Vitamin B12.
- have coronary stents. They should avoid Folate and vitamin B12 supplementation, as it may increase the rate of restenosis.
- are scheduled for laboratory blood tests. Biotin supplements might interfere with some laboratory test results.

Vitamins and minerals obtained from other supplements should be taken into account when prescribing VITAMIN B COMPLEX CAPSULES.

4.5. Interaction with other medicines and other forms of interaction
VITAMIN B COMPLEX CAPSULES may interact with other medicines.
Caution is advised when used concurrently with the following medicine:

- Lithium may inhibit the absorption of B vitamins and folic acid, leading to lower levels in the body.
- The effect of levodopa (when taken without carbidopa), phenytoin and phenobarbital may be reduced by vitamin B6.
- Taking vitamin B2 along with tetracyclines might decrease the effects of tetracyclines. To avoid this interaction, take vitamin B2 supplements two hours before or four hours after taking tetracyclines.
- Vitamin B3 might interfere with high blood pressure medication. It may cause blood pressure to go too low.
- Vitamin B6 along with amiodarone might increase sensitivity to sunlight and increase the possibility of sunburn, blistering, or rashes on areas of skin exposed to sunlight. Patients should be advised to use sunblock and protective clothing.
- Folic acid might decrease the effectiveness of anticonvulsant medicine like phenytoin, primidone and also anti-parasitic medicine like pyrimethamine.
- Taking choline with atropine might decrease the effects of atropine.
- Vitamin B2 may theoretically decrease the effectiveness of broad-spectrum antibiotics (quinolones or tetracyclines).

4.6. Fertility, pregnancy and lactation
The effect of VITAMIN B COMPLEX CAPSULES on fertility, pregnancy and lactation has not yet been established

4.7. Effects on ability to drive and use machines
No studies on the effects on the ability to drive or use machinery have been performed. Patients should exercise caution before driving or the use of machinery until they are reasonably certain VITAMIN B COMPLEX CAPSULES does not adversely affect their performance.

4.8. Undesirable effects
Tabulated summary of adverse reactions:

System Organ Class	
Gastrointestinal disorders	
Frequency unknown:	Gastrointestinal disturbances, Diarrhoea, Nausea, Vomiting
Immune system disorders	
Frequency unknown:	Hypersensitivity reaction
Nervous system disorders	
Frequency unknown	Headaches, Dizziness, Drowsiness
Skin and subcutaneous tissue disorders	
Frequency unknown	Rash or itching (pruritus)

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https//www.sahpra.org.za/Publications/Index/8

4.9. Overdose
In overdose, side effects as indicated in Section 4.8, can be precipitated and/or be of increased severity.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties
Dietary deficiency of vitamins can result in a decrease in overall vitality. Supplementation with VITAMIN B COMPLEX CAPSULES may rectify and prevent relevant deficiencies.
B vitamins help to convert carbohydrates, fats, and protein into energy.
They also play a role in the nervous system, and they are necessary for good brain function.
Vitamin B1 is an essential micronutrient that is required for energy production. Vitamin B2, Vitamin B5 & Vitamin B6 contributes to tissue formation.
Vitamin B3 Contributes to normal growth and development.

Vitamin B6 (Pyridoxine) is an essential micronutrient that is required for the creation of red blood cells and neurotransmitters.
Biotin plays a role in the Kreb's cycle during the production of energy. Biotin not only assists in various metabolic chemical conversions, but also helps with the transfer of carbon dioxide,
Choline helps to support liver function.
Vitamin B12 (Cyanocobalamin) is required for the development, myelination, and function of the central nervous system and healthy red blood cell formation.
Folic Acid contributes to maternal tissue growth during pregnancy and assist in the formation of red blood cells.
Choline supports liver function.

5.2. Pharmacokinetic properties
Pharmacokinetic studies on VITAMIN B COMPLEX CAPSULES as a combination product have not been conducted due to the complexity associated with the number of active ingredients. B vitamins is water-soluble vitamins that is mainly excreted in the urine. (Yellow coloured urine might be noticed)

5.3. Preclinical safety data
There are no other known preclinical safety data of relevance to the prescriber which are additional to that already included in other sections.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Magnesium stearate, Microcrystalline Cellulose and Silicon Dioxide.

6.2. Incompatibilities
Not applicable

6.3. Shelf life
2 years

6.4. Special precautions for storage
Store below 25°C, in a dry place in the original container

6.5. Nature and contents of container
HDPE container with a flip top lid, a foam insert and a silica gel desiccant. The container is sealed with a pressure seal. Pack size of 30 capsules.

6.6. Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
GNC South Africa (Pty) Ltd, Central office park No.4, 257 Jean Avenue, Centurion, 0157.

8. REGISTRATION NUMBER(S)
To be allocated by SAHPRA upon registration

9. DATE OF FIRST AUTHORISATION
To be allocated by SAHPRA upon registration.

GNCVBC/PI-01/AUG24