

PROFESSIONAL INFORMATIONScheduling status: S0

D34.1 Amino Acid; 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 GABA CAPSULES****2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains:

Gama-Aminobutyric Acid	375 mg
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For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules

Clear gelatine capsule containing an off-white powder.

4. CLINICAL PARTICULARS**4.1. Therapeutic indications**

GABA CAPSULES is a supplement specifically formulated to activate receptors critical for brain function. GABA contains Gamma-Aminobutyric Acid, an amino acid that functions as the primary inhibitory neurotransmitter in the central nervous system (CNS) and helps regulate brain activity to promote feelings of calmness and relaxation.

4.2. Posology and method of administrationPosology*Adults 18 years and older:*

Take two (2) to six (6) capsules daily after a meal or as prescribed by a healthcare professional. 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 the ingredients.
- Patients who are pregnant or breastfeeding their baby.

4.4. Special warnings and precautions for use

Take care in patients who:

- are using hypertension medication.

4.5. Interaction with other medicines and other forms of interaction

Patients with chronic conditions or those taking any chronic medication should consult a medical practitioner before taking GABA CAPSULES. Not all possible interactions with other medications may be included in this leaflet.

Caution is advised when used concurrently with the following medicine:

- Hypertension medication. Blood pressure should be monitored closely to avoid hypotension.

4.6. Fertility, pregnancy, and lactation

The effect of GABA CAPSULES on fertility is not known. Not indicated for women who are pregnant or breastfeeding their baby.

4.7. Effects on ability to drive and use machines.

No studies on the effects on the ability to drive or use of machinery have been performed. It is not always possible to predict to what extent GABA CAPSULES may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GABA CAPSULES affects them.

Supplements that contain GABA might cause drowsiness or light-headedness (dizziness).

4.8 Undesirable effects

Tabulated summary of adverse reactions:

System Organ Class	
Cardiac disorder	
<i>Frequency unknown:</i>	Hypotension
Central Nervous System Disorders	
<i>Frequency unknown</i>	Dizziness, Drowsiness

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>

4.8. 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

Gamma-aminobutyric acid is a major inhibitory neurotransmitter in the central nervous system. Gaba-aminobutyric acid blocks, or inhibits, certain brain signals and decreases activity in the nervous system. When GABA attaches to a protein in the brain known as a GABA receptors, it produces a calming effect. It might assist with feelings of anxiety, stress, and fear.

5.2. Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on GABA CAPSULES.

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 HDPE flip top lid, a foam insert, and a silica gel desiccant. The container is sealed with a heat induction seal. Pack size of 60 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.