

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.1 Amino acids

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

GABA, 60 Capsules

COMPOSITION

Each one (1) capsules of GABA contain the following actives:
GABA (Gamma-amino butyric acid) 500 mg

Inactive Ingredients: Vegetarian Capsule (hydroxypropyl methylcellulose) This product is gluten and dairy free (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

GABA assists in calming and supporting the nervous system and may promote a restful and relaxed state.

Ingredients	Uses for ingredient
GABA (Gamma-amino butyric acid)	It slows down your brain by blocking specific signals in your central nervous system (your brain and spinal cord). GABA is known for producing a calming effect. It's thought to play a major role in controlling nerve cell hyperactivity associated with anxiety, stress and fear.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take GABA if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Inherited disorders of amino acid metabolism, high blood pressure. If you are taking the following medication, please consult with your healthcare professional before taking: oral diabetes medicine, medicines that reduce stomach acid, blood pressure medication. If any of the following happens, stop using GABA and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing;



These are all very serious effects. If you have them, you may have had a serious reaction to GABA. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- Burning feeling in throat, Slight shortness of breath, Skin tingling sensation.

These are all very serious effects. If you have them, you may have had a serious reaction to GABA. You may need urgent medical attention or hospitalisation.

Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur.

Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
- Do not share medication with any other person.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor should your condition worsen or does not improve.

DO NOT USE THIS PRODUCT:

- If you are hypersensitive (allergic) to any of the ingredients listed.
- Do not accept this package if seals are broken.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See **Warnings & Special precautions**)

DOSAGE AND DIRECTIONS FOR USE

Adults: Take one (1) capsule daily with a meal or as directed by your healthcare practitioner.

Do not take more than the recommended dose.

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

Treatment:

Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

Do not use after the expiry date stated on the bottle.

Do not use GABA if you notice visible signs of deterioration.

IDENTIFICATION

Vegetable Capsule.

PRESENTATION

A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

This medicine has not been evaluated by SAHPRA for quality, safety, or intended use.

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:

Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,
Sandton, 2146
Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **50**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.1 Aminasure

HANDELSNAAM EN DOSEERVORM,

GABA, 60 Kapsules

SAMESTELING

Elke (1) tablet GABA bevat die volgende aktiewe stowwe:

GABA (Gamma-aminobottersuur) 500 mg

Onaktiewe bestanddele: Vegetariese kapsule (hidroksipropiel-metielcellulose)

Hierdie produk is gluten- en suiwelvry (Suikervry)

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

GABA help om die senuweestelsel te kalmeer en te ondersteun en kan 'n rustige en ontspanne toestand bevorder.

Bestanddele	Gebruike vir bestanddeel
GABA (Gamma-aminoboterzuur)	Dit vertraag jou brein deur spesifieke seine in jou sentrale senuweestelsel (jou brein en rugmurg) te blokkeer. GABA is bekend daarvoor dat dit 'n kalmerende effek lewer. Daar word vermoed dat dit 'n groot rol speel in die beheer van senuweeselhiperaktiwiteit wat met angs, stres en vrees geassosieer word.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie GABA neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan praat voordat jy hierdie aanvulling neem.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Oorerflike afwykings van aminosuurmetabolisme, hoë bloeddruk. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: bloeddruk medisyne. As enige van die volgende gebeur, hou op om GABA te gebruik en vertel jou dokter of gaan na die ongevallen-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling,;

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op GABA gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Neuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Brandende gevoel in keel, effense kortasem, tingelende sensasie van die vel.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op GABA gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind.

Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie medisyne met enige ander persoon deel nie.
- Vra jou apteker of jy meer inligting of advies benodig.
- Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

• As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.

• Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere

aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê.

(Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwasse Neem een (1) kapsule daaglik saam met 'n maaltyd, of soos voorgeskryf deur jou gesondheidspraktisyn.

Moenie meer as die aanbevole dosis neem nie.

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie aanvulling, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien nuwe-effekte.

Behandeling:

Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskermt teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangeduid word nie.

Moenie GABA gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Vegetariese kapsule.

AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksiesêel, peuterkrimpseël, spons en silikagelsakkie.

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSADRES VAN APPLIKANT

Versprei deur:

Amipro Advanced Development Products (Pty) Ltd

Unit 3, Eastgate Business Park, 1 South Road,

Eastgate Extension,

Sandton, 2146,

Tel: 011- 802-8101

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.