

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### GLUTAGENICS®, 250 g Powder

#### COMPOSITION

Each one (1) scoop of GLUTAGENICS® contains the following actives:

L-Glutamine	3.5 g
Deglycyrrhizinized Licorice ( <i>Glycyrrhiza glabra</i> ) [Root 10:1 Extract]	500 mg
Aloe ( <i>Aloe vera</i> ) [Leaf 200:1 Powder]	50 mg

**Inactive Ingredients:** : Natural flavours.

**This product is suitable for vegetarians, dairy, gluten free and non-GMO. (Sugar Free)**

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

GLUTAGENICS® is designed to support the integrity and healthy function of the gastrointestinal lining which is essential for proper digestion, immune function, and overall health. The concentrated licorice extract has been processed to remove glycyrrhizin, which has been associated with sodium and water retention.

Ingredients	Uses for ingredient
L-Glutamine	Glutamine is important for removing excess ammonia (a common waste product in the body). It also helps your immune system function and may be needed for normal brain function and digestion.
Deglycyrrhizinized Licorice ( <i>Glycyrrhiza glabra</i> )	Another type of licorice, called DGL or deglycyrrhizinated licorice, does not seem to have the same side effects and is sometimes used to treat peptic ulcers, canker sores, and reflux (GERD).
Aloe ( <i>Aloe vera</i> )	Oral use of aloe is promoted for weight loss, diabetes, hepatitis, and inflammatory bowel disease.

#### CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take GLUTAGENICS® 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. Stop taking GLUTAGENICS® at least two weeks before scheduled surgery.

#### WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: : Liver disease, Bipolar disorder, Monosodium glutamate (MSG) sensitivity, Seizures, Heart conditions, Hormone-sensitive conditions such as breast cancer, uterine cancer, ovarian cancer, endometriosis, or uterine fibroids, High blood pressure, A muscle condition caused by nerve problems (hypertonia), Low potassium levels in the blood (hypokalaemia), Kidney disease, Intestinal conditions such as Crohn disease, ulcerative colitis, or obstruction. If you are taking the following medication, please consult with your healthcare practitioner before taking: Medications used to prevent seizures (Anticonvulsants), Digoxin (Lanoxin), Oestrogens, Water pills (Loop diuretics), high blood pressure (Antihypertensive drugs), anti-inflammatories (Corticosteroids), Warfarin (Coumadin), Water pills (Diuretic drugs), Midazolam (Versed), diabetes (Antidiabetes drugs), Stimulant laxatives. If any of the following happens, stop using GLUTAGENICS® 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 GLUTAGENICS®. 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):

- nausea/vomiting, constipation, loss of appetite, mental/mood changes, unusual tiredness.

These are all very serious effects. If you have them, you may have had a serious reaction to GLUTAGENICS®. 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:** Mix one (1) scoop with water 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 GLUTAGENICS® if you notice visible signs of deterioration.

#### IDENTIFICATION

Light beige powder.

#### PRESENTATION

A 450 g jar, with a 51 mm cap and a 5 ml scoop.

#### 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: Dissipline Spesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

## GLUTAGENICS®, 250 g Poer

### SAMESTELING

Elke (1) skep GLUTAGENICS® bevat die volgende aktiewe stowwe:

L-Glutamien	3,5 g
Ontglyseriniseerde Soethout (Wortel 10:1 Uittreksel)	500 mg
Aloë (Blaar 200:1 Poer)	50 mg

**Onkiewe bestanddele:** Natuurlike geurmiddels

**Hierdie produk is geskik vir vegetariërs, suiwel, glutenry en nie-GO. (Suikervry)**

### FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

### AANDUIDING EN FARMAKOLOGIESE WERKING

**GLUTAGENICS®** is ontwerp om die integriteit en gesonde funksie van die gastro-intestinale voering te ondersteun, wat noodsaaklik is vir behoorlike vertering, immuunfunksie, en algehele gesondheid. Die gekonsentreerde soethout-uittreksel is verwerk om glisirrhzin te verwyder, wat geassosieer word met natrium- en waterretensie.

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **GLUTAGENICS®** 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):

- naarheid / braking, hardlywigheid, verlies aan eetlus, geestelike / gemoedsveranderinge, ongewone moegheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **GLUTAGENICS®** 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

**Volwassenes:** Meng een (1) skep met water 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 medisyne, 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.

### BEKENE 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.

Beskermer teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moenie nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie **GLUTAGENICS®** gebruik as u sigbare tekens van agteruitgang opmerk nie.

### IDENTIFIKASIE

Ligte bruin poer.

### AANBIEDING

'n Pot van 450 g, met 'n dop van 51 mm en 'n lepel van 5 ml.

### 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 BESIGHEIDSAADRES 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.

Bestanddele	Gebruik vir bestanddeel
L-glutamien	Glutamien is belangrik vir die verwydering van oortollige ammoniak ('n algemene afvalproduk in die liggaam). Dit help ook jou immuunstelsel funksioneer en kan nodig wees vir normale breinfunksie en vertering.
Ontglyseriniseerde Soethout	'n Ander soort drop, genaamd DGL of deglycyrrhizinated drop, blyk nie dieselfde nuwe-effekte te hê nie en word soms gebruik om maagere en reflux (GERD) te behandel.
Aalwyn (Aloe vera)	Orale gebruik van aalwyn word bevorder vir gewigsverlies, diabetes, hepatitis en inflammatoriese dermsiekte.

### KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **GLUTAGENICS®** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem. Hou op om **GLUTAGENICS®** ten minste twee weke voor die geskeduleerde operasie te neem.

### WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Lewersiekte, Bipolêre versteuring, Mononatriumglutamaat (MSG) sensitiwiteit, Aanvalle, Harttoestande, Hormoonsensitiewe toestande soos borskanker, baarmoederkanker, eierstokkanker, endometriose, of baarmoederfibroïede, Hoë bloeddruk, 'n Spiertoestand wat veroorsaak word deur senuweeprobleme (hipertonie), Lae kaliumvlakke in die bloed (hipokalemie), Niersiekte, dermatoestande soos Crohn-siekte, ulseratiewe kolitis of obstruksie.

As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: medisyne wat gebruik word om aanvalle te voorkom (Antikonvulsante), Digoksien (Lanoxin), Estrogeen, Waterpille (Loop diuretika), hoë bloeddruk (Anti-hipertensiewe middels), anti-inflammatoriese middels (Kortikosteroïede), Warfarin (Coumadin), Waterpille (Diuretika), Midazolam (Versed), Diabetes (Antidiabetes middels), Stimulerende laksemiddels. As enige van die volgende gebeur, hou op om **GLUTAGENICS®** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

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