

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### GLUTAGENICS®, 250 g Powder

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- **GLUTAGENICS®** is available without a doctor's prescription.
- Nevertheless, you still need to use **GLUTAGENICS®** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **GLUTAGENICS®** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

#### WHAT IS IN THIS LEAFLET

- What **GLUTAGENICS®** is and what it is used for.
- What you need to know before you take **GLUTAGENICS®**.
- How to take **GLUTAGENICS®**.
- Possible side effects.
- How to store **GLUTAGENICS®**.
- Contents of the pack and other information.

#### WHAT GLUTAGENICS® CONTAINS

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

L-Glutamine	3,5 g
Deglycyrrhizinated 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)

#### WHAT GLUTAGENICS® IS AND WHAT IT IS USED FOR

**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.

#### BEFORE YOU TAKE GLUTAGENICS®

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. 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.

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

#### PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before taking this supplement.

#### DRIVING AND USING MACHINES

It is not always possible to predict to what extent **GLUTAGENICS®** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **GLUTAGENICS®** may affect you.

#### TAKING OTHER MEDICINES WITH GLUTAGENICS®

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner

#### HOW TO TAKE GLUTAGENICS®

Do not share medicines prescribed for you with any other person. Always take **GLUTAGENICS®** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

#### 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.**

#### IF YOU TAKE MORE GLUTAGENICS® THAN YOU SHOULD

In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

Document Reference: GLTGEN.PIL.CMP 11-24



#### IF YOU FORGET TO TAKE GLUTAGENICS®

Do not take a double dose to make up for a missed dose.

#### POSSIBLE SIDE EFFECTS

**GLUTAGENICS®** may have side effects.

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 pills), 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.

Not all side effects and interactions reported for **GLUTAGENICS®** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

#### REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **GLUTAGENICS®**.

#### STORAGE AND DISPOSING OF GLUTAGENICS®

Store all medicines out of the reach of children.

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

Protect from direct sunlight and heat.

Store in the original packaging.

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

Do not use **GLUTAGENICS®** if you notice visible signs of deterioration.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

#### PRESENTATION OF GLUTAGENICS®

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

#### IDENTIFICATION OF GLUTAGENICS®

Light beige powder.

#### REGISTRATION NUMBER –

To be allocated by SAHPRA upon registration.

#### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

#### THIS LEAFLET WAS LAST REVISED ON

19 November 2024

#### NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

Ampiro Advanced Development Products (Pty) Ltd  
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Sandton, 2146  
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# PASİENT INLIGTINGSBLAD

SKEDULERINGSSTATUS 50

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline Spesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

## GLUTAGENICS®, 250 g Poer

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

- **GLUTAGENICS®** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **GLUTAGENICS®** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **GLUTAGENICS®** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **GLUTAGENICS®** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **GLUTAGENICS®** neem.
- Hoe om **GLUTAGENICS®** te neem.
- Moontlike nuwe-effekte.
- Hoe om **GLUTAGENICS®** te bêre.
- Inhoud van die pak en ander inligting

WAT **GLUTAGENICS®** BEVAT

Eke een (1) skep **GLUTAGENICS®** bevat die volgende aktiewe:

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

**Onkiewe bestanddele:** Natuurlike geurmiddels

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

**WAT IS GLUTAGENICS® KAPSULE EN WAARVOOR WORD DIT GEBRUIK**

**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 glisirrhizin te verwyder, wat geassosieer word met natrium- en waterretensie.

**VOORDAT JY GLUTAGENICS® NEEM**

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.

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

**SWANGERSKAP EN BORSVOEDING**

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

**BESTUUR EN GEBRUIK VAN MASIENE**

Dit is nie altyd moontlik om te voorspel in watter mate **GLUTAGENICS®** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **GLUTAGENICS®** jou beïnvloed.

**NEEM VAN ANDER MEDISYNE SAAM MET GLUTAGENICS®**

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie.

**HOE OM GLUTAGENICS® TE NEEM**

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **GLUTAGENICS®** presies soos beskryf in hierdie inligtingsblad, of soos u apteker, gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

**Aanwysings vir gebruik:**

**Volwassenes:** Meng een (1) skep met water of soos voorgeskryf deur jou gesondheidspraktisyn.

**Moenie meer as die aanbevole dosis neem nie.**

**AS JY MEER GLUTAGENICS® NEEM AS WAT JY MOET**

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

**AS JY VERGEET OM GLUTAGENICS® TE NEEM**

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

**MOONTLIKE NUWE-EFFEKTE**

**GLUTAGENICS®** kan nuwe-effekte hê.

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, toestandsoos 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 (Antihipertensiewe middels), anti-inflammatoriese middels (Kortikosteroïede), Warfarin (Coumadin), Waterpille (Diuretika), Midazolam (Versed), Diabetes (Antidiabetes middels), Stimulerende lakseermiddels. 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;

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

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan u gesondheidsorgpraktisyn as dit voortduur):

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

Nie alle nuwe-effekte en interaksies wat vir **GLUTAGENICS®** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. 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.

**AANMELDING VAN NUWE-EFFEKTE**

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook nuwe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **GLUTAGENICS®**.

**HOE OM GLUTAGENICS® TE BÊRE**

Bêre alle medisyne buite bereik van kinders.

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

Beskermt teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

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

Moenie **GLUTAGENICS®** gebruik as u sigbare tekens van agteruitgang opmerk nie. Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

**AANBIEDING VAN GLUTAGENICS®**

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

**IDENTIFIKASIE VAN GLUTAGENICS®**

Ligte bruin poeler.

**REGISTRASIE NOMMER**

Om deur SAHPRA toegestaan te word by registrasie.

**TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING**

Skandeer QR-kode:

**HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP**

19 November 2024

**NAAM EN ADRES VAN REGISTRASIEHOUER**

Versprei deur:

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