

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

GLUTACLEAR[®], 60 & 120 Tablets

COMPOSITION

Each one (1) tablet of GLUTACLEAR[®] contains the following actives:

Vitamin B3 (as Niacinamide)	375 mg
L-Cysteine (as N-acetyl-L-cysteine)	375 mg
Vitamin C (as ascorbic acid)	250 mg
Selenium (as selenomethionine)	37.5 mcg
Broccoli (Brassica oleracea L. var. italica) [Seed] Extract (providing 2,5 mg glucoraphanin)	19,25 mg

Inactive Ingredients: : Microcrystalline cellulose, cellulose, stearic acid (vegetable), silica, and coating (hypromellose, medium-chain triglycerides, and hydroxypropylcellulose)

This product is non-GMO. (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

GLUTACLEAR[®] features a blend of key ingredients designed to help support the body's production of glutathione, a primary antioxidant throughout the entire body. Glutathione plays an important role in protecting the body against oxidative stress and supporting liver detoxification processes.

Ingredients	Uses for ingredient
Vitamin B3 (as Niacinamide)	Niacin (vitamin B3) plays an important role in maintaining the health of your heart, blood vessels, and metabolism.
L-Cysteine (as N-acetyl-L-cysteine)	N-acetyl-L-cysteine is the acetylated form of L-cysteine, which renders it more absorbable. N-acetyl-L-cysteine is also used in cough syrups due to its mucolytic properties.
Vitamin C (as ascorbic acid)	It helps the body make collagen, an important protein used to make skin, cartilage, tendons, ligaments, and blood vessels.
Selenium (as selenomethionine)	Selenium, along with other minerals, can help boost white blood cells, which improves the body's ability to fight illness and infection.
Broccoli (Brassica oleracea L. var. italica)	Phytoconstituents of B. oleracea var. capitata have various pharmacological effects, including antidiabetic, anticancer, antihypertensive, anticholesterolemic, antioxidant, anti-inflammatory, antibacterial, anti-obesity, anticoagulant, and hepatoprotective.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take GLUTACLEAR[®] 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 GLUTACLEAR[®] 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: : Allergies, Chest pain (angina), Diabetes, Gallbladder disease, Gout, Kidney disease, Liver disease, Low blood pressure, Stomach or intestinal ulcers, Thyroid disorders, Asthma, Bleeding disorder, Alcohol use disorder, Chronic kidney disease, A metabolic deficiency called "glucose-6-phosphate dehydrogenase" (GGPD) deficiency, Kidney stones, Autoimmune diseases, Hemodialysis, Fertility problems in males, Skin cancer. If you are taking the following medication, please consult with your healthcare practitioner before taking: Diabetes (Antidiabetes drugs), lowering cholesterol (Bile acid sequestrants, statins), high blood pressure (Antihypertensive drugs), Medications that can harm the liver (Hepatotoxic drugs), slow blood clotting (Anticoagulant / Antiplatelet drugs), Thyroid hormone, Nicotine patch (Nicoderm), Aspirin, Nitroglycerin, Activated charcoal, Chloroquine (Aralen), Oestrogens, Medications for cancer (Alkylating agents), Acetaminophen (Tylenol, others), Sedative medications (Barbiturates), Medications that decrease the immune system (Immunosuppressants), Birth control pills (Contraceptive drugs). If any of the following happens, stop using GLUTACLEAR[®] 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 GLUTACLEAR[®]. 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 GLUTACLEAR[®]. 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) tablet daily with food, 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 GLUTACLEAR[®] if you notice visible signs of deterioration.

IDENTIFICATION

White, coated oval tablet.

PRESENTATION

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

120 TABLETS - A white 250 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: S0

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline Spesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

GLUTACLEAR®, 60 & 120 Tablette

SAMESTELING

Elke (1) tablet GLUTACLEAR® bevat die volgende aktiewe stowwe:

Vitamiën B3 (as Niacinamide)	375 mg
L-sisteien (as N-asetiel-L-sisteien)	375 mg
Vitamiën C (as askorbiensuur)	250 mg
Selenium (as selenometionien)	37,5 mcg
Broccoli (Brassica oleracea L. var. italica) [Saad]	19,25 mg
Uittreksel (verskaf 2,5 mg glucoraphanin)	

Onaktiewe bestanddele: Mikrokristallyne sellulose, sellulose, stearynsuur (groente), silika en laag (hipromellose, mediumketting triglisieriede, en hidroksipropylsellulose)

Hierdie produk is nie-GGO. (Suikervry)

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

GLUTACLEAR® beskik 'n mengsel van sleutelbestanddele wat ontwerp is om die liggaam se produksie van glutathion, 'n primêre antioksidant deur die hele liggaam, te ondersteun. Glutathion speel 'n belangrike rol in die beskerming van die liggaam teen oksidatiewe stres en die ondersteuning van lewerontgiftingsprosesse.

Bestanddele	Gebruike vir bestanddeel
Vitamiën B3 (as Niacinamide)	Niasien (vitamiën B3) speel 'n belangrike rol in die handhawing van die gesondheid van jou hart, bloedvate en metabolisme.
L-sisteien (as N-asetiel-L-sisteien)	N-asetiel-L-sisteien is die asetileerde vorm van L-sisteien, wat dit meer absorbeerbaar maak. N-asetiel-L-sisteien word ook in hoeststroop gebruik as gevolg van sy mukolitiese eienskappe.
Vitamiën C (as askorbiensuur)	Dit help die liggaam om kollageen te maak, 'n belangrike proteïen wat gebruik word om vel, kraakbeen, senings, ligamente en bloedvate te maak.
Selenium (as selenometionien)	Selenium, saam met ander minerale, kan help om witbloedselle 'n hupstoot te gee, wat die liggaam se vermoë om siektes en infeksies te beveg, verbeter.
Broccoli (Brassica oleracea L. var. italica)	Fitobestanddele van B. oleracea var. capitata het verskeie farmakologiese effekte, insluitend anti-diabetiese, antikanker, antihipertensiewe, anticholesteroliese, antioksidante, anti-inflammatoriese, antibakteriese, anti-vetsug, antikoagulante en hepatobeskermdende.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie GLUTACLEAR® 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 GLUTACLEAR® ten minste twee weke voor die geskeduleerde operasie te neem.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Allergieë, borspyn (angina), diabetes, galblaasiekte, jig, niersiekte, lewersiekte, lae bloeddruk, maag- of dermsere, skildklierafwykings, asma, bloedingsversteuring, alkoholgebruiksversteuring, chroniese niersiekte, 'n metaboliese getok genaamd "glukose-6-fosfaat dehidrogenase" (GGPD) tekort, nierstene, Outo-immuun siektes, hemodialise, vrugbaarheidsprobleme by mans, velkanker.

As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Diabetes (Antidiabetes middels), verlaging van cholesterol (Galsuursekwestrants, statiene), hoë bloeddruk (Antihypertensiewe middels), medisyne wat die lewer kan benadeel (Hepatotoksiese middels), stadige bloedsstolling (Antikoagulante / Antiplaatjie-middels), Skildklierhormoon, Nikotienpleister (Nicoderm), Aspirien, Nitroglycieren, Geaktiveerde houtskool, Chlorokien (Aralen), Estrogeen, medisyne vir kanker (Alkileringsmiddels), Acetaminophen (Tylenol, ander), Kalmeermiddels (Barbiturate), medisyne wat die immuunstelsel verminder (immuunonderdrukkers), Geboortebeperkingspille (Voorbehoedmiddels). As enige van die volgende gebeur, hou op om GLUTACLEAR® 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 GLUTACLEAR® 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 GLUTACLEAR® 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 voorsorgmatreëls**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwassenes: Neem daagliks een (1) tablet saam met kos, of soos aangedui deur jou gesondheidsorgpraktisyn.

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.

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.

Beskermer teen direkte sonlig en hitte.

Bêre in die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermdende dop na elke gebruik.

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

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

IDENTIFIKASIE

Wit, bedekte ovaal tablet.

AANBIEDING

60 TABLETTE - 'n Wit 175 ml HDPE-bottel met 'n wit dop, induksiesel, peuterkrimpsel, spons en slikgagsakke.

120 TABLETTE - 'n Wit 250 ml HDPE-bottel met 'n wit dop, induksiesel, peuterkrimpsel, spons en slikgagsakke.

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 BESIGHEIDSADES 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.